Dated: May 24, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–11384 Filed 5–27–21; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Eye Institute Special Emphasis Panel; NEI Clinical Trials and Clinical Applications I.

Date: June 24, 2021.

Time: 11:00 a.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Eye Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 3400, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jennifer C Schiltz, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, National Eye Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 3400, Bethesda, MD 20817, 240–276–5864, *jennifer.schiltz@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: May 24, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–11294 Filed 5–27–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Eye Institute Special Emphasis Panel; NEI Clinical Trials and Clinical Applications II.

Date: June 28, 2021.

Time: 10:00 a.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Eye Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 3400, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jennifer C. Schiltz, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, National Eye Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 3400, Bethesda, MD 20817, 240–276–5864, *jennifer.schiltz@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: May 24, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–11293 Filed 5–27–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2020–0016]

Pandemic Response Voluntary Agreement Under Section 708 of the Defense Production Act; Plans of Action To Respond to COVID–19

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice.

SUMMARY: The Federal Emergency Management Agency (FEMA) announces the formation of four Plans of Action under the Voluntary Agreement for the Manufacture and Distribution of Critical Healthcare Resources Necessary to Respond to a Pandemic: Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Diagnostic Test Kits and other Testing Components to Respond to COVID–19; Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Drug Products, Drug Substances, and Associated Medical Devices to Respond to COVID–19; Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Medical Devices to Respond to COVID–19; and Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Medical Gases to Respond to COVID–19. This notice contains the text of all four Plans of Action.

FOR FURTHER INFORMATION CONTACT: Robert Glenn, Office of Business, Industry, Infrastructure Integration, via email at *OB3I@fema.dhs.gov* or via phone at (202) 212–1666.

SUPPLEMENTARY INFORMATION:

Background and Legal Authority

The Defense Production Act (DPA), 50 U.S.C. 4501 *et seq.*, authorizes the making of ''voluntary agreements and plans of action'' with, among others, representatives of industry and business to help provide for the national defense.[1] The President's authority to facilitate voluntary agreements was delegated to the Secretary of Homeland Security with respect to responding to the spread of COVID–19 within the United States in Executive Order 13911.[2] The Secretary of Homeland Security has further delegated this authority to the FEMA Administrator.[3]

On August 17, 2020, after the appropriate consultations with the Attorney General and the Chairman of the Federal Trade Commission and after requesting and considering public comments, FEMA completed and published in the **Federal Register** a ''Voluntary Agreement, Manufacture and Distribution of Critical Healthcare Resources Necessary to Respond to a

[1] 50 U.S.C. 4558(c)(1).

[2] 85 FR 18403 (Apr. 1, 2020).

[3] DHS Delegation 09052, Rev. 00.1 (Apr. 1, 2020); DHS Delegation Number 09052 Rev. 00 (Jan. 3, 2017).

Pandemic'' (Voluntary Agreement).[4] Unless terminated earlier, the Voluntary Agreement is effective until August 17, 2025, and may be extended subject to additional approval by the Attorney General after consultation with the Chairman of the Federal Trade Commission. The Voluntary Agreement may be used to prepare for or respond to any pandemic, including COVID–19, during that time.

FEMA is now activating four Plans of Action under the Voluntary Agreement:

(1) Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Diagnostic Test Kits and other Testing Components to Respond to COVID–19. The primary goal of the Plan is to create a mechanism to immediately meet exigent requests for Diagnostic Test Kits and other Testing Components anywhere in the Nation and to ensure that actions to support stockpiling of Diagnostic Test Kits and other Testing Components do not interfere with immediate requirements.

(2) Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Drug Products, Drug Substances, and Associated Medical Devices to Respond to COVID–19. The primary goal of the Plan is to create a mechanism to immediately meet exigent requests for Drug Products, Drug Substances, and Associated Medical Devices anywhere in the Nation and to ensure that actions to support Drug Products, Drug Substances, and Associated Medical Devices stockpiling and reserves do not interfere with immediate requirements that would result in an unacceptable risk to healthcare providers or other potential recipients of Drug Products, Drug Substances, and Associated Medical Devices.

(3) Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Medical Devices to Respond to COVID–19. The primary goal of the Plan is to create a mechanism to immediately meet exigent Medical Device requests anywhere in the Nation and to ensure that actions to support Medical Device stockpiling and reserves do not interfere with immediate requirements that would result in an unacceptable risk to healthcare providers or other potential Medical Device recipients.

(4) Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Medical Gases to Respond to COVID–19. The primary purpose of this Plan is to create a mechanism to immediately meet exigent Medical Gas requests anywhere in the Nation and to ensure that actions to support Medical Gas stockpiling and reserves do not interfere with immediate requirements that would result in an unacceptable risk to healthcare providers or other potential Medical Gas recipients.

Appropriate members of the private sector will be invited to join each Plan of Action as Sub-Committee Participants. Provided that a Sub-Committee Participant acts in accordance with the terms of a Plan, the DPA affords the Participant a defense to civil and criminal action brought under the antitrust laws (or any similar law of any state) for actions taken to carry out the Plan. The Plans are designed to foster a close working relationship among FEMA, HHS, and Sub-Committee Participants to address national defense needs through cooperative action under the direction and active supervision of FEMA.

The Attorney General, in consultation with the Chairman of the Federal Trade Commission, has made the required finding for each Plan of Action that the purposes of section 708(c)(1) of the DPA cannot reasonably be achieved without each Plan of Action, or by Plans of Action having less anticompetitive effects than the proposed Plans of Action. Pursuant to section 708(f)(1)(B) of the DPA, the Department of Justice separately published the findings for these Plans of Action in the **Federal Register**. The FEMA Administrator has certified in writing that each Plan of Action is necessary to help provide for the national defense.

[4] Voluntary Agreement Under Section 708 of the Defense Production Act; Manufacture and Distribution of Critical Healthcare Resources Necessary to Respond to a Pandemic, 85 FR 50035, 50035 (Aug. 17, 2020). The Attorney General, in consultation with the Chairman of the Federal Trade Commission, made the required finding that the purpose of the Voluntary Agreement may not reasonably be achieved through an agreement having less anticompetitive effects or without any voluntary agreement and published the finding in the **Federal Register** on the same day. 85 FR 50049 (Aug. 17, 2020).

Text of the Plan of Action To Establish a National Strategy for the Manufacture, Allocation, and Distribution of Diagnostic Test Kits and Other Testing Components To Respond to COVID–19 Implemented Under the Voluntary Agreement for the Manufacture and Distribution of Critical Healthcare Resources Necessary To Respond to a Pandemic

Plan of Action To Establish a National Strategy for the Manufacture, Allocation and Distribution of Diagnostic Test Kits and Other Testing Components To Respond to COVID–19 Implemented Under the Voluntary Agreement for the Manufacture and Distribution of Critical Healthcare Resources Necessary To Respond to a Pandemic

Preface

Pursuant to section 708 of the Defense Production Act of 1950 (DPA), as amended (50 U.S.C. 4558), the Federal Emergency Management Agency (FEMA) Administrator (Administrator), after consultation with the Secretary of the Department of Health and Human Services (HHS), the Attorney General of the United States (Attorney General), and the Chair of the Federal Trade Commission (FTC), developed a Voluntary Agreement for the Manufacture and Distribution of Critical Healthcare Resources Necessary to Respond to a Pandemic (Voluntary Agreement), 85 FR 50035 (August 17, 2020). The Voluntary Agreement, which operates through a series of Plans of Action, maximizes the manufacture and efficient distribution of Critical Healthcare Resources nationwide to respond to a pandemic by establishing unity of effort between Participants and the Federal Government for integrated coordination, planning, information sharing with FEMA, as authorized by FEMA, and allocation and distribution of Critical Healthcare Resources.

This document establishes a Plan of Action (Plan) to Establish a National Strategy for the Manufacture, Allocation and Distribution of Diagnostic Test Kits and other Testing Components to Respond to COVID–19. This Plan will be implemented under the Voluntary Agreement by several Sub-Committees.

(1) Sub-Committee to Define Requirements for COVID–19 Diagnostic Test Kits and other Testing Components,

(2) Sub-Committee for Lab-Based Testing,

(3) Sub-Committee for Point-of-Care Testing,

(4) Sub-Committee for At-Home Testing,

(5) Sub-Committee for Swabs (Nasal & Throat), and

(6) Sub-Committee for Transfer Media and Pipette Tips.

The Sub-Committee to Define Requirements for COVID–19 Diagnostic Test Kits and other Testing Components will be formed first. FEMA may establish additional Sub-Committees under this Plan, so long as:

(1) The Sub-Committee addresses one specific and well-defined category of item needed for COVID–19 testing; and

(2) The Sub-Committee is recommended by the Sub-Committee to Define Requirements for COVID–19 Diagnostic Test Kits and other Testing Components.

The purpose of the Plan is to maximize the manufacture and efficient distribution of Diagnostic Test Kits and other Testing Components and create a prioritization protocol for End-Users based upon their demonstrated or projected requirements including geographic and regional circumstances. The primary goal of the Plan is to create a mechanism to immediately meet exigent requests for Diagnostic Test Kits and other Testing Components anywhere in the Nation and to ensure that actions to support stockpiling of Diagnostic Test Kits and other Testing Components do not interfere with immediate requirements. When the requirements of the Plan are met, it affords Sub-Committee Participants defenses to civil and criminal actions brought under the antitrust laws (or any similar law of any state) for actions taken within the scope of the Plan. The Plan is designed to foster a close working relationship among FEMA, HHS, and Sub-Committee Participants to address national defense needs through cooperative action under the direction and active supervision of FEMA.

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I. Purpose

A pandemic may present conditions that pose a direct threat to the national defense of the United States or its preparedness programs such that, pursuant to DPA section 708(c)(1), an agreement to collectively coordinate, plan, and collaborate for the manufacture and distribution of Diagnostic Test Kits and other Testing Components is necessary for the national defense. This Plan of Action to Establish a National Strategy for the Manufacture, Allocation and Distribution of Diagnostic Test Kits and other Testing Components to Respond to COVID–19 is established under the Voluntary Agreement and establishes six Sub-Committees to oversee and implement the Plan. The Plan and Sub-Committees will optimize the manufacture and the efficient distribution of selected types of Diagnostic Test Kits and other Testing Components and create a prioritization protocol for End-Users based upon their demonstrated or projected requirements.

II. Authorities

Section 708, Defense Production Act (50 U.S.C. 4558); sections 402(2) & 501(b), Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121–5207); sections 503(b)(2)(B) & 504(a)(10) & (16) of the Homeland Security Act of 2002 (6 U.S.C. 313(b)(2)(B), 314(a)(10) & (16)); sections 201, 301, National Emergencies Act (50 U.S.C. 1601 *et seq.*); section 319, Public Health Service Act (42 U.S.C. 247d); Executive Order (E.O.) 13911, 85 FR 18403 (March 27, 2020); Prioritization and Allocation of Certain Scarce or Threatened Health and Medical Resources for Domestic Use, 85 FR 20195 (April 10, 2020). Pursuant to DPA section 708(f)(1)(A), the Administrator certifies that this Plan is necessary for the national defense.

III. General Provisions

A. Definitions

Administrator

The FEMA Administrator is the Sponsor of the Voluntary Agreement. Pursuant to a delegation or redelegation of the functions given to the President by DPA section 708, the Administrator proposes and provides for the development and carrying out of the Voluntary Agreement, including through the development and implementation of Plans of Action. The Administrator is responsible for carrying out all duties and responsibilities required by 50 U.S.C. 4558 and 44 CFR part 332 and for appointing one or more Chairpersons to manage and administer the Committee and all Sub-Committees formed to carry out the Voluntary Agreement.

Agreement

The Voluntary Agreement for the Manufacture and Distribution of Critical Healthcare Resources Necessary to Respond to a Pandemic (Voluntary Agreement).

Allocation

The process of determining and directing the relative distribution among one or more competing requests from End-Users for the same Diagnostic Test Kits and other Testing Components. Through the Allocation process, FEMA—with participation from Sub-Committee Participants—will assess the actual needs of End-Users and determine how to divide the available and projected supply of Diagnostic Test Kits and other Testing Components to minimize impacts to life, safety, and economic disruption associated with shortages of Diagnostic Test Kits and other Testing Components. Allocation will take place only under Exigent

Circumstances. FEMA retains decision-making authority for all Allocation under this Plan.

Attendees

Subject matter experts, invited by the Chairperson or a Sub-Committee Chairperson to attend meetings authorized under the Voluntary Agreement or this Plan, to provide technical advice or to represent other government agencies or interested parties. Invitations to attendees will be extended as required for Committee or Sub-Committee meetings and deliberations.

Chairperson

FEMA senior executive(s), appointed by the Administrator, to chair the Committee for the Distribution of Healthcare Resources Necessary to Respond to a Pandemic (Committee). The Chairperson shall be responsible for the overall management and administration of the Committee, the Voluntary Agreement, and Plans of Action developed under the Voluntary Agreement while remaining under the supervision of the Administrator; shall initiate, or approve in advance, each meeting held to discuss problems, determine policies, recommend actions, and make decisions necessary to carry out the Voluntary Agreement; appoint one or more co-Chairpersons to chair the Committee, and otherwise shall carry out all duties and responsibilities assigned to him. With the approval of the Administrator, the Chairperson may create one or more Sub-Committees, and may appoint one or more Sub-Committee Chairpersons to chair the Sub-Committees, as appropriate.

Committee

Committee for the Distribution of Healthcare Resources Necessary to Respond to a Pandemic established under the Voluntary Agreement.

Competitively Sensitive Information

Competitively Sensitive Information that is shared pursuant to this Plan may include any Document or other tangible thing or oral transmission that contains financial, business, commercial, scientific, technical, economic, or engineering information or data, including, but not limited to

- financial statements and data,
- customer and supplier lists,
- price and other terms of sale to customers,
- sales records, projections and forecasts,
- inventory levels,
- capacity and capacity utilization,
- cost information,
- sourcing and procurement information,
- manufacturing and production information,
- delivery and shipping information,
- systems and data designs, and
- methods, techniques, processes, procedures, programs, codes, or similar information,

whether tangible or intangible, and regardless of the method of storage, compilation, or recordation, if the owner thereof has taken reasonable measures to protect the information from disclosure to the public or competitors. These measures may be evidenced by marking or labeling the items as ''competitively sensitive information'' during submission to FEMA or in the Participant's customary and existing treatment of such information (regardless of labeling).

All Competitively Sensitive Information provided by a Sub-Committee Participant as described herein is deemed Competitively Sensitive Information, except for Information that:

a. Is published or has been made publicly available at the time of disclosure by the Sub-Committee Participant;

b. was in the possession of, or was lawfully and readily available to, FEMA from another source at the time of disclosure without breaching any obligation of confidentiality applicable to the other source; or

c. was independently developed or acquired without reference to or reliance upon the Sub-Committee Participant's Competitively Sensitive Information;

Where information deemed Competitively Sensitive Information is required to be disclosed by law, regulation, or court order, the ''Competitively Sensitive'' (or substantially similar) label will continue to attach to all information and portion(s) of documents that are not made public through the required disclosure.

Diagnostic Test Kit

Defined as any ''drug'' or ''device'' under the United States Food, Drug, and Cosmetic Act, 21 U.S.C. 321(g) or (h), respectively, used for detection or identification of the novel coronavirus in any individual.

Document

Any information, on paper or in electronic/audio/visual format, including written, recorded, and graphic materials of every kind, in the possession, custody, or control of the Participant and used or shared in the course of participation in the Voluntary Agreement or a subsequent Plan of Action.

End-User

This includes all direct and ancillary medical support including, but not limited to, hospitals, independent healthcare providers, nursing homes, medical laboratories, independent physician offices, first responders, alternate care facilities and the general public that reasonably represents the totality of the nation's response to COVID–19.

Exigent Circumstances

As determined by the Chairperson, the actual or forecasted shortage of a particular type of Diagnostic Test Kit or other Testing Component which likely cannot be fulfilled via usual market mechanisms for an acute, critical time period, and where immediate and substantial harm is projected to occur from lack of intervention.

Pandemic

A Pandemic is defined as an epidemic that has spread to human populations across a large geographic area that is subject to one or more declarations under the National Emergencies Act, the Public Health Service Act, or the Robert T. Stafford Disaster Relief and Emergency Assistance Act, or if the Administrator determines that one or more declarations is likely to occur and the epidemic poses a direct threat to the national defense or its preparedness programs. For example, Coronavirus Disease 2019 (COVID–19).

Participant

An individual, partnership, corporation, association, or private organization, other than a federal agency, that has substantive capabilities, resources or expertise to carry out the purpose of the Voluntary Agreement, that has been specifically invited to participate in the Voluntary Agreement by the Chairperson, and that has applied and agreed to the terms of the Voluntary Agreement. ''Participant'' includes a corporate or non-corporate entity entering into the Voluntary Agreement and all subsidiaries and affiliates of that entity in which that entity has 50 percent or more control either by stock ownership, board majority, or otherwise. The Administrator may invite Participants to join the Voluntary Agreement at any time during its effective period.

Plan of Action (Plan)

This document. A documented method, pursuant to 50 U.S.C.

4558(b)(2), proposed by FEMA to implement a particular set of activities under the Voluntary Agreement, through a Sub-Committee focused on a particular Critical Healthcare Resource, or pandemic response workstream or functional area necessary for the national defense.

Plan of Action Agreement

A separate commitment made by Participants upon invitation and agreement to participate in a Plan of Action as part of one or more Sub-Committees. Completing the Plan of Action Agreement confers responsibilities on the Participant consistent with those articulated in the Plan and affords Participants a defense against antitrust claims under section 708 for actions taken to develop or carry out the Plan and the appropriate Sub-Committee(s), as described in Section IV below.

Representatives

The representatives the Administrator identifies and invites to the Committee from FEMA, HHS, and other federal agencies with equities in this Plan, and empowered to speak on behalf of their agencies' interests. The Attorney General and the Chair of the FTC, or their delegates, may also attend any meeting as a Representative.

Sub-Committee

A body formed by the Administrator from select Participants to implement a Plan of Action.

Sub-Committee Chairperson

FEMA executive, appointed by the Chairperson, to chair a Sub-Committee to implement a Plan of Action. The Sub-Committee Chairperson shall be responsible for the overall management and administration of the Sub-Committee in furtherance of this Plan while remaining under the supervision of the Administrator and the Chairperson.

Sub-Committee Members

Collectively the Sub-Committee Chairperson(s), Representatives, and Sub-Committee Participants. Jointly responsible developing and executing this Plan.

Sub-Committee Participant

A subset of Participants of the Committee, that have been specifically invited to participate in a Sub-Committee by the Sub-Committee Chairperson, and that have applied and agreed to the terms of this Plan and signed the Plan of Action Agreement. The Sub-Committee Chairperson may invite Participants in the Committee to join a Sub-Committee as a Sub-Committee Participant at any time during the Plan's effective period.

Testing Components

Defined as any article needed to support the transportation, storage, distribution, or administration of a Diagnostic Test Kit or subsequent result. Common Testing Components include collection swabs, transport media and pipette tips, but other associated materials may be included, if and as appropriate.

B. Plan of Action Participation

This Plan will be implemented under the Voluntary Agreement by one or more Sub-Committees.

(1) Sub-Committee to Define Requirements for COVID–19 Diagnostic Test Kits and other Testing Components,

(2) Sub-Committee for Lab-Based Testing,

(3) Sub-Committee for Point-of-Care Testing,

(4) Sub-Committee for At-Home Testing,

(5) Sub-Committee for Swabs (Nasal & Throat), and

(6) Sub-Committee for Transfer Media and Pipette Tips.

The Sub-Committee to Define Requirements for COVID–19 Diagnostic Test Kits and other Testing Components will be formed first. FEMA may establish additional Sub-Committees under this Plan, so long as:

(1) The Sub-Committee addresses one specific and well-defined category of item needed for COVID–19 testing; and

(2) The Sub-Committee is recommended by the Sub-Committee to Define Requirements for COVID–19 Diagnostic Test Kits and other Testing Components.

Each Sub-Committee will consist of the (1) Sub-Committee Chairperson(s), (2) Representatives from FEMA, HHS, the Department of Justice (DOJ), and other federal agencies with equities in this Plan, and (3) Sub-Committee Participants that have substantive capabilities, resources or expertise to carry out the purpose of this Plan and have signed the Plan of Action Agreement. The Chairperson shall invite Sub-Committee Participants who, in his or her determination, are reasonably representative of the appropriate industry or segment of such industry. Other Attendees—invited by the Sub-Committee Chairperson as subject matter experts to provide technical advice or to represent the interests of other government agencies or interested parties—may also participate in Sub-Committee meetings. The naming of these Sub-Committees does not commit the Administrator to creating them unless and until circumstances dictate.

C. Effective Date and Duration of Participation

This Plan is effective immediately upon satisfaction of the requirements of DPA section 708(f)(1). This Plan shall remain in effect until terminated in accordance with 44 CFR 332.4. It shall be effective for no more than five (5) years from August 17, 2020, when the requirements of DPA section 708(f)(1) were satisfied for the Voluntary Agreement, unless otherwise terminated pursuant to DPA section 708(h)(9) and 44 CFR 332.4 or extended as set forth in DPA section 708(f)(2). No action may take place under this Plan until it is activated, as described in Section III(E), below.

D. Withdrawal

Participation in the Plan is voluntary, as is the acceptance of most obligations under the Plan. Sub-Committee Participants may withdraw from this Plan or from an individual Sub-Committee at any point, subject to the fulfillment of obligations previously agreed upon by the Participant prior to the date of withdrawal. Note that the obligations outlined in V.B regarding information management and associated responsibilities apply once a party has shared or received information through a Sub-Committee and remain in place after the party's withdrawal from the Sub-Committee or Plan. If a Sub-Committee Participant indicates an intent to withdraw from the Plan due to a modification or amendment of the Plan (described below), the Sub-Committee Participant will not be required to perform actions directed by that modification or amendment. *Withdrawal from the Plan will automatically trigger withdrawal from all Sub-Committees; however, a Participant may withdraw from a Sub-Committee without also withdrawing from the Plan or other Sub-Committees.* To withdraw from the Plan or from an individual Sub-Committee, a Participant must provide written notice to the Administrator at least fifteen (15) calendar days prior to the effective date of that Sub-Committee Participant's withdrawal specifying the scope of withdrawal. Following receipt of such notice, the Administrator will inform the other Sub-Committee Participants of the date and the scope of the withdrawal.

Upon the effective date of the withdrawal from the Plan, the Sub-Committee Participant must cease all

activities under the Plan. Upon the effective date of the withdrawal from one or more Sub-Committee(s), the Sub-Committee Participant must cease all activities under the Plan that pertain to the withdrawn Sub-Committee(s).

E. Plan of Action Activation and Deactivation

The Administrator, in consultation with the Chairperson and Sub-Committee Chairperson, will invite a select group of Participants in the Voluntary Agreement to form the following Sub-Committees, beginning with the Sub-Committee to Define Requirements for COVID–19 Diagnostic Test Kits and other Testing Components, which will be responsible for implementing this Plan.

(1) Sub-Committee to Define Requirements for COVID–19 Diagnostic Test Kits and other Testing Components,

(2) Sub-Committee for Lab-Based Testing,

(3) Sub-Committee for Point-of-Care Testing,

(4) Sub-Committee for At-Home Testing,

(5) Sub-Committee for Swabs (Nasal & Throat), and

(6) Sub-Committee for Transfer Media and Pipette Tips.

The Sub-Committee to Define Requirements for COVID–19 Diagnostic Test Kits and other Testing Components will be formed first. FEMA may establish additional Sub-Committees under this Plan, so long as:

(1) The Sub-Committee addresses one specific and well-defined category of item needed for COVID–19 testing; and

(2) The Sub-Committee is recommended by the Sub-Committee to Define Requirements for COVID–19 Diagnostic Test Kits and other Testing Components.

This Plan will be activated for each invited Participant when the Participant executes a Plan of Action Agreement, and a Participant may not participate in a Sub-Committee until the Plan of Action Agreement is executed. Participants will be invited to join this Plan at the discretion of the Chairperson or the Sponsor to the Voluntary Agreement. Participants will be further invited to attend specific meetings of one or more Sub-Committees at the discretion of the Chairperson.

F. Rules and Regulations

Sub-Committee Participants acknowledge and agree to comply with all provisions of DPA section 708, as amended, and regulations related thereto which are promulgated by FEMA, the Department of Homeland Security, HHS, the Attorney General, and the FTC. FEMA has promulgated standards and procedures pertaining to voluntary agreements in 44 CFR part 332. The Administrator shall inform Participants of new rules and regulations as they are issued.

G. Modification and Amendment

The Administrator, after consultation with the Attorney General and the Chair of the FTC, may terminate or modify, in writing, this Plan at any time. The Attorney General, after consultation with the Chair of the FTC and the Administrator, may terminate or modify, in writing, this Plan at any time. Sub-Committee Participants may propose modifications or amendments to the Plan or to the Sub-Committees at any time.

Where possible, material modifications to the Plan or a Sub-Committee will be subject to a 30-calendar day delayed implementation and opportunity for notice and comment by Sub-Committee Participants to the Chairperson. This delayed implementation period may be shortened or eliminated if the Administrator deems it necessary. The Administrator shall inform Sub-Committee Participants of modifications or amendments to the Plan or to the Sub-Committees as they are proposed and issued.

The Administrator, after consultation with the Attorney General and the Chair of the FTC, may remove Sub-Committee Participants from the Plan or from a Sub-Committee at any time. The Attorney General, after consultation with the Chair of the FTC and the Administrator, may remove Sub-Committee Participants from this Plan or from a Sub-Committee at any time. If a Participant is removed from the Plan or from a Sub-Committee, the Participant may request written notice of the reasons for removal from the Chairperson, who shall provide such notice in a reasonable time period.

H. Expenses

Participation in this Plan or in a Sub-Committee does not confer funds to Sub-Committee Participants, nor does it limit or prohibit any pre-existing source of funds. Unless otherwise specified, all expenses, administrative or otherwise, incurred by Sub-Committee Participants associated with participation in this Plan or a Sub-Committee shall be borne exclusively by the Sub-Committee Participants.

I. Record Keeping

Each Sub-Committee Chairperson shall have primary responsibility for maintaining records in accordance with 44 CFR part 332 and shall be the official custodian of records related to carrying out this Plan. Each Sub-Committee Participant shall maintain for five years all minutes of meetings, transcripts, records, documents, and other data, including any communications with other Sub-Committee Participants or with any other member of the Sub-Committee, including drafts, related to the carrying out of this Plan or incorporating data or information received in the course of carrying out this Plan. Each Sub-Committee Participant agrees to produce to the Administrator, the Attorney General, and the Chair of the FTC upon request any item that this section requires the Participant to maintain. Any record maintained in accordance with 44 CFR part 332 shall be available for public inspection and copying, unless exempted on the grounds specified in 5 U.S.C. 552(b)(1), (3) or (4) or identified as privileged and confidential information in accordance with DPA section 705(d), and 44 CFR 332.5.

IV. Antitrust Defense

Under the provisions of DPA subsection 708(j), each Sub-Committee Participant in this Plan shall have available as a defense to any civil or criminal action brought for violation of the antitrust laws (or any similar law of any State) with respect to any action to develop or carry out this Plan, that such action was taken by the Sub-Committee Participant in the course of developing or carrying out this Plan, that the Sub-Committee Participant complied with the provisions of DPA section 708 and the rules promulgated thereunder, and that the Sub-Committee Participant acted in accordance with the terms of the Voluntary Agreement and this Plan. Except in the case of actions taken to develop this Plan, this defense shall be available only to the extent the Sub-Committee Participant asserting the defense demonstrates that the action was specified in, or was within the scope of, this Plan and within the scope of the appropriate Sub-Committee(s), including being taken at the direction and under the active supervision of FEMA.

This defense shall not apply to any actions taken after the termination of this Plan. Immediately upon modification of this Plan, no defense to antitrust claims under Section 708 shall be available to any subsequent action that is beyond the scope of the modified Plan. The Sub-Committee Participant asserting the defense bears the burden of proof to establish the elements of the defense. The defense shall not be

available if the person against whom the defense is asserted shows that the action was taken for the purpose of violating the antitrust laws.

V. Terms and Conditions

As the sponsoring agency, FEMA will maintain oversight over Sub-Committee activities and direct and supervise actions taken to carry out this Plan, including by retaining decision-making authority over actions taken pursuant to the Plan to ensure such actions are necessary to address a direct threat to the national defense. The Attorney General and the Chair of the FTC will monitor activities of the Sub-Committees to ensure they execute their responsibilities in a manner consistent with this Plan and their actions have the least anticompetitive effects possible.

A. Plan of Action Execution

This Plan will be used to support the following objectives to respond to a Pandemic by maximizing the manufacture and efficient distribution of selected types of Diagnostic Test Kits and other Testing Components and creating a prioritization protocol for End-Users based upon their demonstrated or projected requirements. Each Sub-Committee will undertake the following Objectives for the Diagnostic Test Kits and other Testing Components within its area of jurisdiction.

1. Objectives

(1) Optimize the timely production of sufficient quantities of Diagnostic Test Kits and other Testing Components, as part of the overall national strategy, to reduce transmission of COVID–19 and mitigate the impacts caused by it.

(2) Identify and encourage the development of Diagnostic Test Kits and Testing Components that can identify more than one illness (*e.g.,* flu, strep throat or other bacterial infections, common cold, seasonal allergies, and COVID–19).

(3) Identify and encourage the development of Diagnostic Test Kits and Testing Components that can mitigate supply chain constraints, by leveraging new technologies and different components.

(4) Ensure Diagnostic Test Kits and other Testing Components are distributed effectively and equitably across the whole community nationally based on necessity and risk.

(5) Balance restoration and maintenance of the nation's stockpile of Diagnostic Test Kits and other Testing Components with near-term requirements.

(6) Establish a process for FEMA Allocation of Diagnostic Test Kits and other Testing Components nationwide.

(7) Evaluate supply chain components to determine national vulnerabilities and propose corrective actions to improve resiliency in the manufacture and distribution of Diagnostic Test Kits and other Testing Components.

(8) Ensure ongoing competition in the manufacture and distribution of Diagnostic Test Kits and other Testing Components to the greatest extent possible under the DPA.

2. Actions

Sub-Committee Participants may be asked to support these objectives by taking the following specific actions:

(1) Assist the Chairperson in identifying which types of Diagnostic Test Kits and other Testing Components should be included within each Sub-Committee. Identification will be based upon each item's importance to the national response to COVID–19 and whether it can be reasonably inferred, based upon the best evidence available, that the current and projected supply measured against current and projected demand may not adequately meet the requirements of all identified End-Users or regional or geographic areas of the country.

(2) Provide input to the Chairperson in creating a prioritized list of End Users of Diagnostic Test Kits and other Testing Components, by category of End User, for each type of Diagnostic Test Kits and other Testing Components identified by each Sub-Committee, and ascertaining the relative demand and supply of Diagnostic Test Kits and other Testing Components among and within those End User categories. Prioritization shall be decided by the Chairperson, based upon each item's importance, reflecting the consensus views of the Sub-Committee Members that it represents the most effective way to save lives in responding to the COVID–19 pandemic. This list may be updated throughout the life of the Plan based upon either short term or long-term demands. These categories should be considered holistically in terms of the Whole-of-Nation response to COVID–19.

(3) Evaluate the domestic supply of Diagnostic Test Kits and other Testing Components and identify when the expansion of the domestic manufacture of Diagnostic Test Kits and other Testing Components may be necessary, as directed and decided by the Chairperson.

(4) Provide information, assist, and validate, as necessary as decided by the Chairperson, demand projections for Diagnostic Test Kits and other Testing Components.

(5) Create a process for and collaborate in the evaluation of competing claims for Diagnostic Test Kits and/or other Testing Components from End-Users.

(6) Prepare a general strategy to accomplish the activities listed in V(A)(2)(7) below regarding activities in Exigent Circumstances consistent with the decisions made by the Chairperson.

(7) In Exigent Circumstances, with review and concurrence in all possible instances by DOJ in consultation with FTC:

- Facilitate maximum availability of Diagnostic Test Kits and other Testing Components to the nation by deconflicting overlapping demands from the collective Participants' customer base, as directed and decided by the Chairperson.
- Facilitate maximum availability of Diagnostic Test Kits and other Testing Components to the nation by deconflicting overlapping supply chain demands placed upon Members, as directed and decided by the Chairperson.
- Facilitate the efficient distribution of Diagnostic Test Kits and other Testing Components by deconflicting overlapping distribution chain activities of Members, as directed and decided by the Chairperson.
- Create a process for and collaborate in the Allocation of Diagnostic Test Kits and other Testing Components nationwide consistent with the decisions made by the Chairperson.

(8) Provide data and information necessary to validate the efforts of the Sub-Committee including the actual and planned amounts of Diagnostic Test Kits and other Testing Components to be distributed throughout the Nation, as determined by the Chairperson.

(9) Provide feedback to the Sub-Committee on the outcomes of the collective efforts of the Sub-Committee Members and any impediments or bottlenecks.

(10) Advise the Chairperson whether additional Participants or Attendees should be invited to join this Plan and Sub-Committee.

(11) Carry out other activities regarding Diagnostic Test Kits and other Testing Components as identified by Sub-Committees under this Plan as determined and directed by the Chairperson necessary to address the COVID–19 virus' direct threat to the national defense, where such activities have been reviewed and approved by DOJ and FTC and received concurrence from Sub-Committee members.

B. Information Management and Responsibilities

FEMA will request only that data and information from Sub-Committee Participants that is necessary to meet the objectives of the Plan and consistent with the scope of the relevant Sub-Committees. Upon signing a Plan of Action Agreement for this Plan, FEMA requests that Participants endeavor to cooperate with diligence and speed, and to the extent permissible under this Plan, and share with FEMA data and information necessary to meet the objectives of this Plan.

Sub-Committee Participants agree to share with FEMA the following data with diligence and speed, to the extent permissible under this Plan, and abide by the following guidelines, where feasible and consistent with the data that is owned by each Sub-Committee Participant:

(1) In general, Participants will not be asked to share Competitively Sensitive Information directly with other Participants.

(2) FEMA will only request direct sharing of Competitively Sensitive Information among Participants during Exigent Circumstances where there is a mission critical need or timeline such that sharing only through FEMA is impractical or threatens the outcome of the Plan or Sub-Committee action. Such requests, if made, will be only among Participants whose participation is necessary to meet the objectives of the Plan, will be limited in scope to the greatest extent possible, and will be shared only pursuant to safeguards subject to prior review and audit by DOJ and FTC. Direct sharing of Competitively Sensitive Information with other Participants will be limited in scope and circumstances to the greatest extent possible. Participants may not share Competitively Sensitive Information directly with other Participants unless specifically requested by FEMA, in consultation with DOJ and FTC. All Competitively Sensitive Information delivered to FEMA or to another Sub-Committee Participant shall be delivered by secure means, for example, password-protected or encrypted electronic files or drives with the password/key delivered by separate communication or method or via upload to an appropriately secure web portal as directed by FEMA. All data delivered to the web portal designated by FEMA is deemed to be Competitively Sensitive Information.

(3) To allow FEMA to identify and appropriately protect documents containing Competitively Sensitive Information by the Sub-Committee Participant providing the documents, the Sub-Committee Participant will make good faith efforts to designate any Competitively Sensitive Information by placing restrictive markings on documents and things considered to be competitively sensitive, the restrictive markings being sufficiently clear in wording and visibility to indicate the restricted nature of the data. The Sub-Committee Participant will identify Competitively Sensitive Information that is disclosed verbally by oral warning. Information designated as competitively sensitive will, to the extent allowed by law, be presumed to constitute confidential or privileged commercial or financial information, and be provided by the Sub-Committee Participant to FEMA with the expectation that it will be kept confidential by both parties, as such terms are understood in accordance with 5 U.S.C. 552(b)(4) of the Freedom of Information Act and federal judicial interpretations of this statute. FEMA agrees that to the extent any information designated as competitively sensitive by a Sub-Committee Participant is responsive to a request for disclosure under the Freedom of Information Act, FEMA will consult with the Sub-Committee Participant and afford the Participant ten (10) working days to object to any disclosure by FEMA.

(4) FEMA will make good faith efforts to appropriately recognize unmarked Documents containing Competitively Sensitive Information as Competitively Sensitive Information. However, FEMA cannot guarantee that all unmarked Documents will be recognized as being Competitively Sensitive Information and protected from disclosure to third parties. If the unmarked Documents have not been disclosed without restriction outside of FEMA, the Sub-Committee Participant may retroactively request to have appropriate designations placed on the Documents. If the unmarked Documents have been disclosed without restriction outside of FEMA, FEMA will, to the extent practicable, remove any requested information from public forums controlled by FEMA and will work promptly to request that a receiving party return or destroy disclosed unmarked Documents if requested by the Sub-Committee Participant.

(5) Competitively Sensitive Information may be used by FEMA, alone or in combination with additional information, including Documents and Competitively Sensitive Information received from third parties, to support FEMA's implementation of this Plan as determined by the Chairperson. In all situations, FEMA will aggregate and anonymize Competitively Sensitive Information to the greatest extent possible to protect the interests retained by the owners of the data while still allowing the objectives of the Plan and Sub-Committee to be achieved. To the greatest extent possible, such aggregation will render the competitively sensitive nature of the Competitively Sensitive Information of the Sub-Committee Participant no longer recognizable in a commercially sensitive manner, and without sufficient information to enable, by inference or otherwise, attribution to Sub-Committee Participant or its affiliates (as clearly identified and disclosed to FEMA). Any disclosure of Competitively Sensitive Information by FEMA, within or outside a Sub-Committee, will be subject to review and approval by DOJ and FTC.

(6) Except as otherwise expressly permitted by applicable federal law, FEMA shall not disclose any Competitively Sensitive Information or use any Competitively Sensitive Information for any purpose other than in connection with the purposes of this Plan, and FEMA will not sell any Competitively Sensitive Information of any Sub-Committee Participant.

(7) Except as described below, FEMA may disclose Competitively Sensitive Information only to its employees, officers, directors, contractors, agents, and advisors (including attorneys, accountants, consultants, and financial advisors). Any individual with access to Competitively Sensitive Information will be expected to comply with the terms of this Plan.

a. *Information Sharing within the Sub-Committee:* FEMA may share Competitively Sensitive Information with Sub-Committee Participants and Federal Representatives of the Plan, and their respective employees, officers, directors, contractors, agents, and advisors (including attorneys, accountants, consultants, and financial advisors) where there is a need to know and where disclosure is reasonably necessary in furtherance of implementing the Plan. FEMA will aggregate and anonymize data prior to sharing with the Sub-Committee Participants to the greatest extent possible while still allowing the objectives of the Plan to be achieved, and will not share data—particularly to competitors of the submitter—prior to consultation with and approval by the DOJ and FTC.

i. Sub-Committee Participants, when providing Competitively Sensitive Information to FEMA, may request that this Information not be shared with other Sub-Committee Participants. Where these requests are made in good

faith and are reasonable in nature, FEMA will respect these requests to the greatest extent possible and will consult the owner of the data prior to any release made to Sub-Committee Participants.

b. *Restricted Reports.* FEMA may communicate Competitively Sensitive Information to appropriate government officials through Restricted Reports. The information contained in Restricted Reports shall be aggregated and anonymized to the greatest extent possible, while recognizing that these officials may need a certain amount of granularity and specificity of information to appropriately respond to COVID–19. FEMA will aim to aggregate data to the County level, and will not share Restricted Reports prior to consultation and approval from the DOJ and FTC. FEMA may disclose Restricted Reports to relevant White House and Administration officials and State Governors, and their respective employees, officers, directors, contractors, agents, and advisors (including attorneys, accountants, consultants, and financial advisors) who have a need to know and to whom such disclosure is reasonably necessary solely in furtherance of the implementation of this Plan. FEMA shall take appropriate action (by instructions, agreement, or otherwise) to ensure that receiving parties comply with all data-sharing confidentiality and obligations under this Plan as if such persons or entities had been parties to this Plan.

c. *Public Reports.* FEMA may share information with the public through Public Reports. Data contained in Public Reports shall be fully aggregated and anonymized. Public Reports shall be aggregated to at least a state level and may be publicly disclosed after consultation and approval from the DOJ and FTC.

(8) Where possible and not obviated by Exigent Circumstances, FEMA will notify Sub-Committee Participants prior to the release of any Competitively Sensitive Information that has not been fully aggregated and anonymized. In consultation with DOJ and FTC, FEMA will consider any good-faith requests made by Sub-Committee members to hold the release of data or requests for further aggregation or anonymization. In general, FEMA will not provide notification prior to the release of *Public Reports,* under the presumption that the data in these reports has already been fully anonymized and de-identified.

(9) Any party receiving Competitively Sensitive Information through this Plan shall use such information solely for the purposes outlined in the Plan and take steps, such as imposing previously approved firewalls or tracking usage, to prevent misuse of the information. Disclosure and use of Competitively Sensitive Information will be limited to the greatest extent possible, and any party receiving Competitively Sensitive Information shall follow the procedures outlined in paragraph 7 above.

(10) At the conclusion of a Participant's involvement in a Plan—due to the deactivation of the Plan or due to the Participant's withdrawal or removal—each Participant will be requested to sequester any and all Competitively Sensitive Information received through participation in the Plan. This sequestration shall include the deletion of all Competitively Sensitive Information unless required to be kept pursuant to the Record Keeping requirements as described *supra,* Section I, 44 CFR part 332, or any other provision of law.

C. Oversight

Each Sub-Committee Chairperson is responsible for ensuring that the Attorney General, or suitable delegate(s) from the DOJ, and the FTC Chair, or suitable delegate(s) from the FTC, have awareness of activities under this Plan, including activation, deactivation, and scheduling of meetings. The Attorney General, the FTC Chair, or their delegates may attend Sub-Committee meetings and request to be apprised of any activities taken in accordance with activities under this Plan. DOJ or FTC Representatives may request and review any proposed action by the Sub-Committee or Sub-Committee Participants undertaken pursuant to this Plan, including the provision of data. If any DOJ or FTC Representative believes any actions proposed or taken are not consistent with relevant antitrust protections provided by the DPA, he or she shall provide warning and guidance to the Sub-Committee as soon as the potential issue is identified. If questions arise about the antitrust protections applicable to any particular action, FEMA may request DOJ, in consultation with the FTC, provide an opinion on the legality of the action under relevant DPA antitrust protections.

VI. Establishment of the Sub-Committees

This Plan establishes Sub-Committees to implement the Plan to Establish a National Strategy for the Manufacture, Allocation and Distribution of Diagnostic Test Kits and other Testing Components to Respond to COVID–19 to provide the Federal Government and the Participants a forum to maximize the manufacture and efficient distribution of selected types of Diagnostic Test Kits and other Testing Components and to create a prioritization protocol based upon identified types of Diagnostic Test Kits and other Testing Components End-Users and their demonstrated or projected requirements, and demonstrated or projected geographic and regional areas of need. The outcome should include a framework to expeditiously meet any Diagnostic Test Kits and other Testing Components needs in Exigent Circumstances anywhere in the Nation, and to ensure that actions to support the stockpiling of Diagnostic Test Kits and other Testing Components do not interfere with immediate requirements that would result in an unacceptable risk to healthcare providers or other potential Diagnostic Test Kits and other Testing Components recipients. A Sub-Committee Chairperson designated by the Chairperson will convene and preside over each Sub-Committee. Sub-Committees will not be used for contract negotiations or contract discussions between the Participants and the Federal Government; such negotiations or discussions will be in accordance with applicable federal contracting policies and procedures. However, this shall not limit any discussion within a Sub-Committee about the operational utilization of existing and potential contracts between the Participants and Representatives when seeking to align their use with overall manufacturing and distribution efforts consistent with this Plan.

Each Sub-Committee will consist of designated Representatives from FEMA, HHS, other federal agencies with equities in this Plan, and each Sub-Committee Participant. The Attorney General and Chair of the FTC, or their delegates, may also join each Sub-Committee and attend meetings at their discretion. Attendees may also be invited at the discretion of a Sub-Committee Chairperson as subject matter experts, to provide technical advice, or to represent other government agencies, but will not be considered part of the Sub-Committee.

To the extent necessary to respond to the Pandemic, only at the explicit direction of a Sub-Committee Chairperson, and subject to the provisions of Section V(B), Sub-Committee Members may be asked to provide technical advice, share information, help identify and validate places and resources of the greatest need, help project future manufacturing and distribution demands, assist in identifying and resolving the allocation of scarce resources amongst all

necessary public and private sector domestic needs under Exigent Circumstances, and take any other necessary actions to maximize the timely allocation and distribution of Diagnostic Test Kits and other Testing Components as determined necessary by FEMA to respond to the Pandemic. A Sub-Committee Chairperson or his or her designee, at the Sub-Committee Chairperson's sole discretion, will make decisions on these issues in order to ensure the maximum efficiency and effectiveness in the use of Sub-Committee Member's resources. All Sub-Committee Participants will be invited to open Sub-Committee meetings. For selected Sub-Committee meetings, attendance may be limited to designated Sub-Committee Participants to meet specific operational requirements, as determined by FEMA.

Each Sub-Committee Chairperson shall notify the Attorney General, the Chair of the FTC, Representatives, and Participants of the time, place, and nature of each meeting and of the proposed agenda of each meeting to be held to carry out this Plan. Additionally, each Sub-Committee Chairperson shall provide for publication in the **Federal Register** of a notice of the time, place, and nature of each meeting. If a meeting is open, a **Federal Register** notice will be published reasonably in advance of the meeting. A Sub-Committee Chairman may restrict attendance at meetings only on the grounds outlined by 44 CFR 332.5(c)(1)–(3). If a meeting is closed, a **Federal Register** notice will be published within ten (10) days of the meeting and will include the reasons why the meeting is closed pursuant to 44 CFR 332.3(c)(2).

The Sub-Committee Chairperson shall establish the agenda for each meeting, be responsible for adherence to the agenda, and provide for a written summary or other record of each meeting and provide copies of transcripts or other records to FEMA, the Attorney General, the Chair of the FTC, and all Sub-Committee Participants. The Chairperson shall take necessary actions to protect from public disclosure any data discussed with or obtained from Sub-Committee Participants which a Sub-Committee Participant has identified as a trade secret or as privileged and confidential in accordance with DPA sections 708(h)(3) and 705(d), or which qualifies for withholding under 44 CFR 332.5.

VII. Application and Agreement

The Sub-Committee Participant identified below hereby agrees to join in the Federal Emergency Management Agency sponsored Plan of Action to Establish a National Strategy for the Manufacture, Allocation and Distribution of Diagnostic Test Kits and other Testing Components under the Voluntary Agreement for the Manufacture and Distribution of Healthcare Resources Necessary to Respond to a Pandemic and to become a Participant in one or more Sub-Committees established by this Plan. This Plan will be published in the **Federal Register**. This Plan is authorized under section 708 of the Defense Production Act of 1950, as amended. Regulations governing the Voluntary Agreement for the Manufacture and Distribution for the Manufacture and Distribution of Healthcare Resources Necessary to Respond to a Pandemic and all subsequent Plans of Action at 44 CFR part 332. The applicant, as a Sub-Committee Participant, agrees to comply with the provisions of section 708 of the Defense Production Act of 1950, as amended, the regulations at 44 CFR part 332, and the terms of this Plan.

VIII. Assignment

No Sub-Committee Participant may assign or transfer this Plan, in whole or in part, or any protections, rights or obligations hereunder without the prior written consent of the Sub-Committee Chairperson. When requested, the Sub-Committee Chairperson will respond to written requests for consent within 10 (ten) business days of receipt.

_____

(Company name)

_____

(Name of authorized representative)

_____

(Signature of authorized representative)

_____

(Date)

_____

Administrator (Sponsor)

_____

(Date)

Text of the Plan of Action To Establish a National Strategy for the Manufacture, Allocation, and Distribution of Drug Products, Drug Substances, and Associated Medical Devices To Respond to COVID–19 Implemented Under the Voluntary Agreement for the Manufacture and Distribution of Critical Healthcare Resources Necessary To Respond to a Pandemic

Plan of Action To Establish a National Strategy for the Manufacture, Allocation, and Distribution of Drug Products, Drug Substances, and Associated Medical Devices To Respond to COVID–19 Implemented Under the Voluntary Agreement for the Manufacture and Distribution of Critical Healthcare Resources Necessary To Respond to a Pandemic

Preface

Pursuant to section 708 of the Defense Production Act of 1950 (DPA), as amended (50 U.S.C. 4558), the Federal Emergency Management Agency (FEMA) Administrator (Administrator), after consultation with the Secretary of the Department of Health and Human Services (HHS), the Attorney General of the United States (Attorney General), and the Chair of the Federal Trade Commission (FTC), developed a Voluntary Agreement for the Manufacture and Distribution of Critical Healthcare Resources Necessary to Respond to a Pandemic (Voluntary Agreement), 85 FR 50035 (August 17, 2020). The Voluntary Agreement, which operates through a series of Plans of Action, maximizes the manufacture and efficient distribution of Critical Healthcare Resources nationwide to respond to a pandemic by establishing unity of effort between Participants and the Federal Government for integrated coordination, planning, information sharing with FEMA, as authorized by FEMA, and allocation and distribution of Critical Healthcare Resources.

This document establishes a Plan of Action (Plan) to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Drug Products, Drug Substances, and Associated Medical Devices to Respond to COVID–19. This Plan will be implemented under the Voluntary Agreement by several Sub-Committees, beginning with a Sub-Committee to Define Requirements for COVID–19 Drug Products, Drug Substances, and Associated Medical Devices:

(1) Sub-Committee to Define Requirements for COVID–19 Drug Products, Drug Substances, and Associated Medical Devices

(2) Sub-Committee for Monoclonal Antibodies,

(3) Sub-Committee for Drug Products, Drug Substances, and Associated Medical Devices Related to the Treatment of Respiratory Illness,

(4) Sub-Committee for Drug Products, Drug Substances, and Associated Medical Devices Related to Acute and Intensive Care,

(5) Sub-Committee to Accelerate Coronavirus Treatment,

(6) Sub-Committee for Strategic Investment Towards On-Shoring of Pharmaceutical Manufacturing and Fill-Finish, and

(7) Sub-Committee for Emergency Use Authorizations.

FEMA may establish additional Sub-Committees under this Plan, so long as:

(1) The Sub-Committee addresses one specific and well-defined category of Drug Products, Drug Substances, or Associated Medical Devices; and

(2) The Sub-Committee is recommended by the Sub-Committee to Define Requirements for COVID–19 Drug Products, Drug Substances, and Associated Medical Devices.

The purpose of the Plan and the Sub-Committees is to maximize the manufacture and efficient distribution of selected types of Drug Products, Drug Substances, and Associated Medical Devices, and create a prioritization protocol for End-Users based upon their demonstrated or projected requirements including geographic and regional circumstances. The primary goal of the Plan is to create a mechanism to immediately meet exigent requests for Drug Products, Drug Substances, and Associated Medical Devices anywhere in the Nation and to ensure that actions to support Drug Products, Drug Substances, and Associated Medical Devices stockpiling and reserves do not interfere with immediate requirements that would result in an unacceptable risk to healthcare providers or other potential recipients of Drug Products, Drug Substances, and Associated Medical Devices. When the requirements of the Plan are met, it affords Sub-Committee Participants defenses to civil and criminal actions brought under the antitrust laws (or any similar law of any state) for actions taken within the scope of the Plan. The Plan is designed to foster a close working relationship among FEMA, HHS, and Sub-Committee Participants to address national defense needs through cooperative action under the direction and active supervision of FEMA.

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IX. Purpose

A pandemic may present conditions that pose a direct threat to the national defense of the United States or its preparedness programs such that, pursuant to DPA section 708(c)(1), an agreement to collectively coordinate, plan, and collaborate for the manufacture, allocation and distribution of Drug Products, Drug Substances, and Associated Medical Devices is necessary for the national defense. This Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Drug Products, Drug Substances, and Associated Medical Devices to Respond to COVID–19 is established under the Voluntary Agreement and establishes seven Sub-Committees to oversee and implement the Plan. The Plan and Sub-Committees will optimize the manufacture and the efficient distribution of selected types of Drug Products, Drug Substances, and Associated Medical Devices and create a prioritization protocol for End-Users based upon their demonstrated or projected requirements.

X. Authorities

Section 708, Defense Production Act (50 U.S.C. 4558); sections 402(2) & 501(b), Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121–5207); sections 503(b)(2)(B) & 504(a)(10) & (16) of the Homeland Security Act of 2002 (6 U.S.C. 313(b)(2)(B), 314(a)(10) & (16)); sections 201, 301, National Emergencies Act (50 U.S.C. 1601 *et seq.*); section 319, Public Health Service Act (42 U.S.C. 247d); Executive Order (E.O.) 13911, 85 FR 18403 (March 27, 2020); Prioritization and Allocation of Certain Scarce or Threatened Health and Medical Resources for Domestic Use, 85 FR 20195 (April 10, 2020). Pursuant to DPA section 708(f)(1)(A), the Administrator certifies that this Plan is necessary for the national defense.

XI. General Provisions

J. Definitions

Administrator

The FEMA Administrator is the Sponsor of the Voluntary Agreement. Pursuant to a delegation or redelegation of the functions given to the President by DPA section 708, the Administrator proposes and provides for the development and carrying out of the Voluntary Agreement, including through the development and implementation of Plans of Action. The Administrator is responsible for carrying out all duties and responsibilities required by 50 U.S.C. 4558 and 44 CFR part 332 and for appointing one or more Chairpersons to manage and administer the Committee and all Sub-Committees formed to carry out the Voluntary Agreement.

Agreement

The Voluntary Agreement for the Manufacture and Distribution of Critical Healthcare Resources Necessary to

Respond to a Pandemic (Voluntary Agreement).

Allocation

The process of determining and directing the relative distribution among one or more competing requests from End-Users for the same Drug Products, Drug Substances, or Associated Medical Devices. Through the Allocation process, FEMA—with participation from Sub-Committee Participants—will assess the actual needs of End-Users and determine how to divide the available and projected supply of Drug Products, Drug Substances, and Associated Medical Devices to minimize impacts to life, safety, and economic disruption associated with shortages of Drug Products, Drug Substances, and Associated Medical Devices. Allocation will take place only under Exigent Circumstances. Although FEMA retains decision making authority for all Allocation under this Plan, other federal agency partners retain decision-making authority for all assets under their control.

Associated Medical Devices

A device, as defined under the United States Food, Drug, and Cosmetic Act, 21 U.S.C. 321(h), that is used to manufacture, transport, distribute, deliver, sanitize, dispose of, or in any other way facilitate the use of, any drug product or drug substance needed to cure, mitigate or treat COVID–19.

Attendees

Subject matter experts, invited by the Chairperson or a Sub-Committee Chairperson to attend meetings authorized under the Voluntary Agreement or this Plan, to provide technical advice or to represent other government agencies or interested parties. Invitations to attendees will be extended as required for Committee or Sub-Committee meetings and deliberations.

Chairperson

FEMA senior executive(s), appointed by the Administrator, to chair the Committee for the Distribution of Healthcare Resources Necessary to Respond to a Pandemic (Committee). The Chairperson shall be responsible for the overall management and administration of the Committee, the Voluntary Agreement, and Plans of Action developed under the Voluntary Agreement while remaining under the supervision of the Administrator; shall initiate, or approve in advance, each meeting held to discuss problems, determine policies, recommend actions, and make decisions necessary to carry out the Voluntary Agreement; appoint one or more co-Chairpersons to chair the Committee, and otherwise shall carry out all duties and responsibilities assigned to them. With the approval of the Administrator, the Chairperson may create one or more Sub-Committees, and may appoint one or more Sub-Committee Chairpersons to chair the Sub-Committees, as appropriate.

Committee

Committee for the Distribution of Healthcare Resources Necessary to Respond to a Pandemic established under the Voluntary Agreement.

Competitively Sensitive Information

Competitively Sensitive Information that is shared pursuant to this Plan may include any Document or other tangible thing or oral transmission that contains financial, business, commercial, scientific, technical, economic, or engineering information or data, including, but not limited to

- financial statements and data,
- customer and supplier lists,
- price and other terms of sale to customers,
- sales records, projections and forecasts,
- inventory levels,
- capacity and capacity utilization,
- cost information,
- sourcing and procurement information,
- manufacturing and production information,
- delivery and shipping information,
- systems and data designs, and
- methods, techniques, processes, procedures, programs, codes, or similar information,

whether tangible or intangible, and regardless of the method of storage, compilation, or recordation, if the owner thereof has taken reasonable measures to protect the information from disclosure to the public or competitors. These measures may be evidenced by marking or labeling the items as ''competitively sensitive information'' during submission to FEMA or in the Participant's customary and existing treatment of such information (regardless of labeling).

All Competitively Sensitive Information provided by a Sub-Committee Participant as described herein is deemed Competitively Sensitive Information, except for Information that:

a. Is published or has been made publicly available at the time of disclosure by the Sub-Committee Participant;

b. was in the possession of, or was lawfully and readily available to, FEMA from another source at the time of disclosure without breaching any obligation of confidentiality applicable to the other source; or

c. was independently developed or acquired without reference to or reliance upon the Sub-Committee Participant's Competitively Sensitive Information;

Where information deemed Competitively Sensitive Information is required to be disclosed by law, regulation, or court order, the ''Competitively Sensitive'' (or substantially similar) label will continue to attach to all information and portion(s) of documents that are not made public through the required disclosure.

Document

Any information, on paper or in electronic/audio/visual format, including written, recorded, and graphic materials of every kind, in the possession, custody, or control of the Participant and used or shared in the course of participation in the Voluntary Agreement or a subsequent Plan of Action.

Drug Product

Is a finished dosage form, *e.g.,* tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients.

Drug Substance

Is an active ingredient that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the human body, but does not include intermediates used in the synthesis of such ingredient.

End-User

This includes all direct and ancillary medical support including, but not limited to, hospitals, independent healthcare providers, nursing homes, medical laboratories, dental care providers, independent physician offices, first responders, alternate care facilities and the general public that reasonably represents the totality of the nation's response to COVID–19. ''End-User'' may also include essential workers necessary to maintain or restore critical infrastructure operations, including but not limited to law enforcement, education, food and agriculture, energy, water and wastewater, and public works personnel.

Exigent Circumstances

As determined by the Chairperson, the actual or forecasted shortage of a particular type or types of Drug Products, Drug Substances, and Associated Medical Devices which likely cannot be fulfilled via usual market mechanisms for an acute, critical time period, and where immediate and substantial harm is projected to occur from lack of intervention.

Fill-Finish

Fill-finish is the final manufacturing step in the overall drug manufacturing process. This process transfers a sterile drug from a filling needle to a sterile container.

On-Shoring

Building domestic capacity that is otherwise available in other Countries.

Pandemic

A Pandemic is defined as an epidemic that has spread to human populations across a large geographic area that is subject to one or more declarations under the National Emergencies Act, the Public Health Service Act, or the Robert T. Stafford Disaster Relief and Emergency Assistance Act, or if the Administrator determines that one or more declarations is likely to occur and the epidemic poses a direct threat to the national defense or its preparedness programs. For example, Coronavirus Disease 2019 (COVID–19).

Participant

An individual, partnership, corporation, association, or private organization, other than a federal agency, that has substantive capabilities, resources or expertise to carry out the purpose of the Voluntary Agreement, that has been specifically invited to participate in the Voluntary Agreement by the Chairperson, and that has applied and agreed to the terms of the Voluntary Agreement. ''Participant'' includes a corporate or non-corporate entity entering into the Voluntary Agreement and all subsidiaries and affiliates of that entity in which that entity has 50 percent or more control either by stock ownership, board majority, or otherwise. The Administrator may invite Participants to join the Voluntary Agreement at any time during its effective period.

Plan of Action (Plan)

This document. A documented method, pursuant to 50 U.S.C. 4558(b)(2), proposed by FEMA to implement a particular set of activities under the Voluntary Agreement, through a Sub-Committee focused on a particular Critical Healthcare Resource, or pandemic response workstream or functional area necessary for the national defense.

Plan of Action Agreement

A separate commitment made by Participants upon invitation and agreement to participate in a Plan of Action as part of one or more Sub-Committees. Completing the Plan of Action Agreement confers responsibilities on the Participant consistent with those articulated in the Plan and affords Participants a defense against antitrust claims under section 708 for actions taken to develop or carry out the Plan and the appropriate Sub-Committee(s), as described in Section IV below.

Representatives

The representatives the Administrator identifies and invites to the Committee from FEMA, HHS, and other federal agencies with equities in this Plan, and empowered to speak on behalf of their agencies' interests. The Attorney General and the Chair of the FTC, or their delegates, may also attend any meeting as a Representative.

Strategic Investment

Targeted investments for on-shoring of drug product and drug substance manufacturing, including fill-finish capacities.

Sub-Committee

A body formed by the Administrator from select Participants to implement a Plan of Action.

Sub-Committee Chairperson

FEMA official, appointed by the Chairperson, to chair a Sub-Committee to implement a Plan of Action. The Sub-Committee Chairperson shall be responsible for the overall management and administration of the Sub-Committee in furtherance of this Plan while remaining under the supervision of the Administrator and the Chairperson.

Sub-Committee Members

Collectively the Sub-Committee Chairperson(s), Representatives, and Sub-Committee Participants. Jointly responsible developing and executing this Plan.

Sub-Committee Participant

A subset of Participants of the Committee, that have been specifically invited to participate in a Sub-Committee by the Sub-Committee Chairperson, and that have applied and agreed to the terms of this Plan and signed the Plan of Action Agreement. The Sub-Committee Chairperson may invite Participants in the Committee to join a Sub-Committee as a Sub-Committee Participant at any time during the Plan's effective period.

K. Plan of Action Participation

This Plan will be carried out by a subset of the Participants in the Voluntary Agreement through several Sub-Committees:

(1) Sub-Committee to Define Requirements for COVID–19 Drug Products, Drug Substances, and Associated Medical Devices,

(2) Sub-Committee for Monoclonal Antibodies,

(3) Sub-Committee for Drug Products, Drug Substances, and Associated Medical Devices Related to the Treatment of Respiratory Illness,

(4) Sub-Committee for Drug Products, Drug Substances, and Associated Medical Devices Related to Acute and Intensive Care,

(5) Sub-Committee to Accelerate Coronavirus Treatment,

(6) Sub-Committee for Strategic Investment Towards On-Shoring of Pharmaceutical Manufacturing and Fill-Finish, and

(7) Sub-Committee for Emergency Use Authorizations.

FEMA may establish additional Sub-Committees under this Plan, so long as:

(1) The Sub-Committee addresses one specific and well-defined category of Drug Products, Drug Substances, and Associated Medical Devices; and

(2) The Sub-Committee is recommended by the Sub-Committee to Define Requirements for COVID–19 Drug Products, Drug Substances, and Associated Medical Devices.

Each Sub-Committee will consist of the (1) Sub-Committee Chairperson(s), (2) Representatives from FEMA, HHS, the Department of Justice (DOJ), and other federal agencies with equities in this Plan, and (3) Sub-Committee Participants that have substantive capabilities, resources or expertise to carry out the purpose of this Plan and have signed the Plan of Action Agreement. The Chairperson shall invite Sub-Committee Participants who, in his or her determination, are reasonably representative of the appropriate industry or segment of such industry. Other Attendees—invited by the Sub-Committee Chairperson as subject matter experts to provide technical advice or to represent the interests of other government agencies or interested parties—may also participate in Sub-Committee meetings. The naming of these Sub-Committees does not commit

the Administrator to creating them unless and until circumstances dictate.

L. Effective Date and Duration of Participation

This Plan is effective immediately upon satisfaction of the requirements of DPA section 708(f)(1). This Plan shall remain in effect until terminated in accordance with 44 CFR 332.4. It shall be effective for no more than five (5) years from August 17, 2020, when the requirements of DPA section 708(f)(1) were satisfied for the Voluntary Agreement, unless otherwise terminated pursuant to DPA section 708(h)(9) and 44 CFR 332.4 or extended as set forth in DPA section 708(f)(2). No action may take place under this Plan until it is activated, as described in Section III(E), below.

M. Withdrawal

Participation in the Plan is voluntary, as is the acceptance of most obligations under the Plan. Sub-Committee Participants may withdraw from this Plan or from an individual Sub-Committee at any point, subject to the fulfillment of obligations previously agreed upon by the Participant prior to the date of withdrawal. Note that the obligations outlined in V.B regarding information management and associated responsibilities apply once a party has shared or received information through a Sub-Committee, and remain in place after the party's withdrawal from the Sub-Committee or Plan. If a Sub-Committee Participant indicates an intent to withdraw from the Plan due to a modification or amendment of the Plan (described below), the Sub-Committee Participant will not be required to perform actions directed by that modification or amendment. *Withdrawal from the Plan will automatically trigger withdrawal from all Sub-Committees; however, a Participant may withdraw from a Sub-Committee without also withdrawing from the Plan or other Sub-Committees.* To withdraw from the Plan or from an individual Sub-Committee, a Participant must provide written notice to the Administrator at least fifteen (15) calendar days prior to the effective date of that Sub-Committee Participant's withdrawal specifying the scope of withdrawal. Following receipt of such notice, the Administrator will inform the other Sub-Committee Participants of the date and the scope of the withdrawal.

Upon the effective date of the withdrawal from the Plan, the Sub-Committee Participant must cease all activities under the Plan. Upon the effective date of the withdrawal from one or more Sub-Committee(s), the Sub-Committee Participant must cease all activities under the Plan that pertain to the withdrawn Sub-Committee(s).

N. Plan of Action Activation and Deactivation

The Administrator, in consultation with the Chairperson and Sub-Committee Chairperson, will invite a select group of Participants in the Voluntary Agreement to form the following Sub-Committees, beginning with the Sub-Committee to Define Requirements for COVID–19 Drug Products, Drug Substances, and Associated Medical Devices, which will be responsible for implementing this Plan.

(1) Sub-Committee to Define Requirements for COVID–19 Drug Products, Drug Substances, and Associated Medical Devices,

(2) Sub-Committee for Monoclonal Antibodies,

(3) Sub-Committee for Drug Products, Drug Substances, and Associated Medical Devices Related to the Treatment of Respiratory Illness,

(4) Sub-Committee for Drug Products, Drug Substances, and Associated Medical Devices Related to Acute and Intensive Care,

(5) Sub-Committee to Accelerate Coronavirus Treatment,

(6) Sub-Committee for Strategic Investment Towards On-Shoring of Pharmaceutical Manufacturing and Fill-Finish, and

(7) Sub-Committee for Emergency Use Authorizations.

FEMA may establish additional Sub-Committees under this Plan, so long as:

(1) The Sub-Committee addresses one specific and well-defined category of Drug Products, Drug Substances, and Associated Medical Devices; and

(2) The Sub-Committee is recommended by the Sub-Committee to Define Requirements for COVID–19 Drug Products, Drug Substances, and Associated Medical Devices.

This Plan will be activated for each invited Participant when the Participant executes a Plan of Action Agreement, and a Participant may not participate in a Sub-Committee until the Plan of Action Agreement is executed. Participants will be invited to join this Plan at the discretion of the Chairperson or the Sponsor to the Voluntary Agreement. Participants will be further invited to attend specific meetings of one or more Sub-Committees at the discretion of the Chairperson.

O. Rules and Regulations

Sub-Committee Participants acknowledge and agree to comply with all provisions of DPA section 708, as amended, and regulations related thereto which are promulgated by FEMA, the Department of Homeland Security, HHS, the Attorney General, and the FTC. FEMA has promulgated standards and procedures pertaining to voluntary agreements in 44 CFR part 332. The Administrator shall inform Participants of new rules and regulations as they are issued.

P. Modification and Amendment

The Administrator, after consultation with the Attorney General and the Chair of the FTC, may terminate or modify, in writing, this Plan at any time. The Attorney General, after consultation with the Chair of the FTC and the Administrator, may terminate or modify, in writing, this Plan at any time. Sub-Committee Participants may propose modifications or amendments to the Plan or to the Sub-Committees at any time.

Where possible, material modifications to the Plan or a Sub-Committee will be subject to a 30 calendar day delayed implementation and opportunity for notice and comment by Sub-Committee Participants to the Chairperson. This delayed implementation period may be shortened or eliminated if the Administrator deems it necessary. The Administrator shall inform Sub-Committee Participants of modifications or amendments to the Plan or to the Sub-Committees as they are proposed and issued.

The Administrator, after consultation with the Attorney General and the Chair of the FTC, may remove Sub-Committee Participants from the Plan or from a Sub-Committee at any time. The Attorney General, after consultation with the Chair of the FTC and the Administrator, may remove Sub-Committee Participants from this Plan or from a Sub-Committee at any time. If a Participant is removed from the Plan or from a Sub-Committee, the Participant may request written notice of the reasons for removal from the Chairperson, who shall provide such notice in a reasonable time-period.

Q. Expenses

Participation in this Plan or in a Sub-Committee does not confer funds to Sub-Committee Participants, nor does it limit or prohibit any pre-existing source of funds. Unless otherwise specified, all expenses, administrative or otherwise, incurred by Sub-Committee Participants associated with participation in this Plan or a Sub-Committee shall be borne exclusively by the Sub-Committee Participants.

R. Record Keeping

Each Sub-Committee Chairperson shall have primary responsibility for maintaining records in accordance with 44 CFR part 332 and shall be the official custodian of records related to carrying out this Plan. Each Sub-Committee Participant shall maintain for five years all minutes of meetings, transcripts, records, documents, and other data, including any communications with other Sub-Committee Participants or with any other member of the Sub-Committee, including drafts, related to the carrying out of this Plan or incorporating data or information received in the course of carrying out this Plan. Each Sub-Committee Participant agrees to produce to the Administrator, the Attorney General, and the Chair of the FTC upon request any item that this section requires the Participant to maintain. Any record maintained in accordance with 44 CFR part 332 shall be available for public inspection and copying, unless exempted on the grounds specified in 5 U.S.C. 552(b)(1), (3) or (4) or identified as privileged and confidential information in accordance with DPA section 705(d), and 44 CFR 332.5.

XII. Antitrust Defense

Under the provisions of DPA subsection 708(j), each Sub-Committee Participant in this Plan shall have available as a defense to any civil or criminal action brought for violation of the antitrust laws (or any similar law of any State) with respect to any action to develop or carry out this Plan, that such action was taken by the Sub-Committee Participant in the course of developing or carrying out this Plan, that the Sub-Committee Participant complied with the provisions of DPA section 708 and the rules promulgated thereunder, and that the Sub-Committee Participant acted in accordance with the terms of the Voluntary Agreement and this Plan. Except in the case of actions taken to develop this Plan, this defense shall be available only to the extent the Sub-Committee Participant asserting the defense demonstrates that the action was specified in, or was within the scope of, this Plan and within the scope of the appropriate Sub-Committee(s), including being taken at the direction and under the active supervision of FEMA.

This defense shall not apply to any actions taken after the termination of this Plan. Immediately upon modification of this Plan, no defense to antitrust claims under Section 708 shall be available to any subsequent action that is beyond the scope of the modified Plan. The Sub-Committee Participant asserting the defense bears the burden of proof to establish the elements of the defense. The defense shall not be available if the person against whom the defense is asserted shows that the action was taken for the purpose of violating the antitrust laws.

XIII. Terms and Conditions

As the sponsoring agency, FEMA will maintain oversight over Sub-Committee activities and direct and supervise actions taken to carry out this Plan, including by retaining decision-making authority over actions taken pursuant to the Plan to ensure such actions are necessary to address a direct threat to the national defense. The Attorney General and the Chair of the FTC will monitor activities of the Sub-Committees to ensure they execute their responsibilities in a manner consistent with this Plan and their actions have the least anticompetitive effects possible.

A. Plan of Action Execution

This Plan will be used to support the following objectives to respond to a Pandemic by maximizing the manufacture and efficient distribution of selected types of Drug Products, Drug Substances, and Associated Medical Devices and creating a prioritization protocol for End-Users based upon their demonstrated or projected requirements and taking into account geographic and regional circumstances. Each Sub-Committee will undertake the following Objectives for the Drug Products, Drug Substances, and Associated Medical Devices within its area of jurisdiction.

1. Objectives

(1) Optimize the timely production of sufficient quantities of Drug Products, Drug Substances, and Associated Medical Devices to reduce loss of life and transmission of the COVID–19 virus.

(2) Expand domestic manufacturing of Drug Products, Drug Substances, and Associated Medical Devices, including fill-finish capacities.

(3) Ensure Drug Products, Drug Substances, and Associated Medical Devices are distributed effectively across the whole community nationally based on risk.

(4) Balance restoration and maintenance of the nation's stockpile of Drug Products, Drug Substances, and Associated Medical Devices with near-term requirements.

(5) Establish a process for FEMA Allocation of Drug Products, Drug Substances, and Associated Medical Devices nationwide.

(6) Ensure ongoing competition in the manufacture and distribution of Drug Products, Drug Substances, and Associated Medical Devices to the greatest extent possible under the DPA.

2. Actions

Sub-Committee Participants may be asked to support these objectives by taking the following specific actions:

(1) Assist the Chairperson in identifying which types of Drug Products, Drug Substances, and Associated Medical Devices should be included within each Sub-Committee. Identification will be based upon each item's importance to the national response to COVID–19 and whether it can be reasonably inferred, based upon the best evidence available, that the current and projected supply measured against current and projected demand may not adequately meet the Drug Product, Drug Substance, and Associated Medical Device requirements to all identified End-Users or regional or geographic areas of the country as result of measures taken to respond to COVID–19.

(2) Provide input to the Chairperson in creating a prioritized list of Drug Product, Drug Substance, and Associated Medical Device End-Users by categories for each type of Drug Product, Drug Substance, and Associated Medical Device identified by each Sub-Committee, and ascertaining the relative demand and supply of Drug Products, Drug Substances, and Associated Medical Devices among and within those End-User categories. Prioritization shall be decided by the Chairperson, based upon each item's importance, reflecting the consensus views of the Sub-Committee Members that it represents the most effective way to save lives and prevent the transmission of the COVID–19 virus. This list may be updated throughout the life of the Plan based upon either short term or long-term demands. These categories should be considered holistically in terms of the Whole-of-Nation response to COVID–19.

(3) Evaluate the domestic supply of Drug Products, Drug Substances, and Associated Medical Devices and identify when the expansion of the domestic manufacture of Drug Products, Drug Substances, and Associated Medical Devices may be necessary, as directed and decided by the Chairperson.

(4) Provide information, assist, and validate, as necessary as decided by the Chairperson, demand projections for Drug Products, Drug Substances, and Associated Medical Devices.

(5) Create a process for and collaborate in the evaluation of competing claims for Drug Products, Drug Substances, and Associated Medical Devices from End-Users.

(6) Prepare a general strategy to accomplish the activities listed in V(A)(2)(7) below regarding activities in Exigent Circumstances consistent with the decisions made by the Chairperson.

(7) In Exigent Circumstances, with review and concurrence in all possible instances by DOJ in consultation with FTC:

- Facilitate maximum availability of Drug Products, Drug Substances, and Associated Medical Devices to the nation or particular geographies by deconflicting overlapping demands from the collective Participants' customer base, as directed and decided by the Chairperson.
- Facilitate maximum availability of Drug Products, Drug Substances, and Associated Medical Devices to the nation or particular geographies by deconflicting overlapping supply chain demands placed upon Members, as directed and decided by the Chairperson.
- Facilitate the efficient distribution of Drug Products, Drug Substances, and Associated Medical Devices by deconflicting overlapping distribution chain activities of Members, as directed and decided by the Chairperson.
- Create a process for and collaborate in the Allocation of Drug Products, Drug Substances, and Associated Medical Devices nationwide or in particular geographies consistent with the decisions made by the Chairperson.
- Create a process for and collaborate in meeting any other exigent requirements throughout the nation or particular geographies consistent with the overall strategy prepared by this Sub-Committee.
- Create a process for and collaborate in establishing expanded domestic Drug Product, Drug Substance, and Associated Medical Device manufacturing and fill-finish capacities.

(8) Provide data and information necessary to validate the efforts of the Sub-Committee including the actual and planned amounts of Drug Products, Drug Substances, and Associated Medical Devices to be distributed throughout the Nation, as determined by the Chairperson.

(9) Provide feedback to the Sub-Committee on the outcomes of the collective efforts of the Sub-Committee Members and any impediments or bottlenecks.

(10) Advise the Chairperson whether additional Participants or Attendees should be invited to join this Plan and Sub-Committee.

(11) Carry out other activities regarding Drug Products, Drug Substances, and Associated Medical Devices as identified by Sub-Committees under this Plan as determined and directed by the Chairperson necessary to address the COVID–19 virus' direct threat to the national defense, where such activities have been reviewed and approved by DOJ and FTC and received concurrence from Sub-Committee members.

D. Information Management and Responsibilities

FEMA will request only that data and information from Sub-Committee Participants that is necessary to meet the objectives of the Plan and consistent with the scope of the relevant Sub-Committees. Upon signing a Plan of Action Agreement for this Plan, FEMA requests that Participants endeavor to cooperate with diligence and speed, and to the extent permissible under this Plan, and share with FEMA data and information necessary to meet the objectives of this Plan.

Sub-Committee Participants agree to share with FEMA the following data with diligence and speed, to the extent permissible under this Plan, and abide by the following guidelines, where feasible and consistent with the data that is owned by each Sub-Committee Participant:

(1) In general, Participants will not be asked to share Competitively Sensitive Information directly with other Participants.

(2) FEMA will only request direct sharing of Competitively Sensitive Information among Participants during Exigent Circumstances where there is a mission critical need or timeline such that sharing only through FEMA is impractical or threatens the outcome of the Plan or Sub-Committee action. Such requests, if made, will be only among Participants whose participation is necessary to meet the objectives of the Plan, will be limited in scope to the greatest extent possible, and will be shared only pursuant to safeguards subject to prior review and audit by DOJ and FTC. Direct sharing of Competitively Sensitive Information with other Participants will be limited in scope and circumstances to the greatest extent possible. Participants may not share Competitively Sensitive Information directly with other Participants unless specifically requested by FEMA, in consultation with DOJ and FTC. All Competitively Sensitive Information delivered to FEMA or to another Sub-Committee Participant shall be delivered by secure means, for example, password-protected or encrypted electronic files or drives with the password/key delivered by separate communication or method or via upload to an appropriately secure web portal as directed by FEMA. All data delivered to the web portal designated by FEMA is deemed to be Competitively Sensitive Information.

(3) To allow FEMA to identify and appropriately protect documents containing Competitively Sensitive Information by the Sub-Committee Participant providing the documents, the Sub-Committee Participant will make good faith efforts to designate any Competitively Sensitive Information by placing restrictive markings on documents and things considered to be competitively sensitive, the restrictive markings being sufficiently clear in wording and visibility to indicate the restricted nature of the data. The Sub-Committee Participant will identify Competitively Sensitive Information that is disclosed verbally by oral warning. Information designated as competitively sensitive will, to the extent allowed by law, be presumed to constitute confidential or privileged commercial or financial information, and be provided by the Sub-Committee Participant to FEMA with the expectation that it will be kept confidential by both parties, as such terms are understood in accordance with 5 U.S.C. 552(b)(4) of the Freedom of Information Act and federal judicial interpretations of this statute. FEMA agrees that to the extent any information designated as competitively sensitive by a Sub-Committee Participant is responsive to a request for disclosure under the Freedom of Information Act, FEMA will consult with the Sub-Committee Participant and afford the Participant ten (10) working days to object to any disclosure by FEMA.

(4) FEMA will make good faith efforts to appropriately recognize unmarked Documents containing Competitively Sensitive Information as Competitively Sensitive Information. However, FEMA cannot guarantee that all unmarked Documents will be recognized as being Competitively Sensitive Information and protected from disclosure to third parties. If the unmarked Documents have not been disclosed without restriction outside of FEMA, the Sub-Committee Participant may retroactively request to have appropriate designations placed on the Documents. If the unmarked Documents have been disclosed without restriction outside of FEMA, FEMA will, to the extent practicable, remove any requested information from public forums

controlled by FEMA and will work promptly to request that a receiving party return or destroy disclosed unmarked Documents if requested by the Sub-Committee Participant.

(5) Competitively Sensitive Information may be used by FEMA, alone or in combination with additional information, including Documents and Competitively Sensitive Information received from third parties, to support FEMA's implementation of this Plan as determined by the Chairperson. In all situations, FEMA will aggregate and anonymize Competitively Sensitive Information to the greatest extent possible to protect the interests retained by the owners of the data while still allowing the objectives of the Plan and Sub-Committee to be achieved. To the greatest extent possible, such aggregation will render the competitively sensitive nature of the Competitively Sensitive Information of the Sub-Committee Participant no longer recognizable in a commercially sensitive manner, and without sufficient information to enable, by inference or otherwise, attribution to Sub-Committee Participant or its affiliates (as clearly identified and disclosed to FEMA). Any disclosure of Competitively Sensitive Information by FEMA, within or outside a Sub-Committee, will be subject to review and approval by DOJ and FTC.

(6) Except as otherwise expressly permitted by applicable federal law, FEMA shall not disclose any Competitively Sensitive Information or use any Competitively Sensitive Information for any purpose other than in connection with the purposes of this Plan, and FEMA will not sell any Competitively Sensitive Information of any Sub-Committee Participant.

(7) Except as described below, FEMA may disclose Competitively Sensitive Information only to its employees, officers, directors, contractors, agents, and advisors (including attorneys, accountants, consultants, and financial advisors). Any individual with access to Competitively Sensitive Information will be expected to comply with the terms of this Plan.

a. *Information Sharing within the Sub-Committee:* FEMA may share Competitively Sensitive Information with Sub-Committee Participants and Federal Representatives of the Plan, and their respective employees, officers, directors, contractors, agents, and advisors (including attorneys, accountants, consultants, and financial advisors) where there is a need to know and where disclosure is reasonably necessary in furtherance of implementing the Plan. FEMA will aggregate and anonymize data prior to sharing with the Sub-Committee Participants to the greatest extent possible while still allowing the objectives of the Plan to be achieved, and will not share data—particularly to competitors of the submitter—prior to consultation with and approval by the DOJ and FTC.

i. Sub-Committee Participants, when providing Competitively Sensitive Information to FEMA, may request that this Information not be shared with other Sub-Committee Participants. Where these requests are made in good faith and are reasonable in nature, FEMA will respect these requests to the greatest extent possible and will consult the owner of the data prior to any release made to Sub-Committee Participants.

b. *Restricted Reports.* FEMA may communicate Competitively Sensitive Information to appropriate government officials through Restricted Reports. The information contained in Restricted Reports shall be aggregated and anonymized to the greatest extent possible, while recognizing that these officials may need a certain amount of granularity and specificity of information to appropriately respond to COVID–19. FEMA will aim to aggregate data to the County level, and will not share Restricted Reports prior to consultation and approval from the DOJ and FTC. FEMA may disclose Restricted Reports to relevant White House and Administration officials and State Governors, and their respective employees, officers, directors, contractors, agents, and advisors (including attorneys, accountants, consultants, and financial advisors) who have a need to know and to whom such disclosure is reasonably necessary solely in furtherance of the implementation of this Plan. FEMA shall take appropriate action (by instructions, agreement, or otherwise) to ensure that receiving parties comply with all data-sharing confidentiality and obligations under this Plan as if such persons or entities had been parties to this Plan.

c. *Public Reports.* FEMA may share information with the public through Public Reports. Data contained in Public Reports shall be fully aggregated and anonymized. Public Reports shall be aggregated to at least a state level and may be publicly disclosed after consultation and approval from the DOJ and FTC.

(8) Where possible and not obviated by Exigent Circumstances, FEMA will notify Sub-Committee Participants prior to the release of any Competitively Sensitive Information that has not been fully aggregated and anonymized. In consultation with DOJ and FTC, FEMA will consider any good-faith requests made by Sub-Committee members to hold the release of data or requests for further aggregation or anonymization. In general, FEMA will not provide notification prior to the release of *Public Reports,* under the presumption that the data in these reports has already been fully anonymized and de-identified.

(9) Any party receiving Competitively Sensitive Information through this Plan shall use such information solely for the purposes outlined in the Plan and take steps, such as imposing previously approved firewalls or tracking usage, to prevent misuse of the information. Disclosure and use of Competitively Sensitive Information will be limited to the greatest extent possible, and any party receiving Competitively Sensitive Information shall follow the procedures outlined in paragraph 7 above.

(10) At the conclusion of a Participant's involvement in a Plan—due to the deactivation of the Plan or due to the Participant's withdrawal or removal—each Participant will be requested to sequester any and all Competitively Sensitive Information received through participation in the Plan. This sequestration shall include the deletion of all Competitively Sensitive Information unless required to be kept pursuant to the Record Keeping requirements as described *supra,* Section I, 44 CFR part 332, or any other provision of law.

E. Oversight

Each Sub-Committee Chairperson is responsible for ensuring that the Attorney General, or suitable delegate(s) from the DOJ, and the FTC Chair, or suitable delegate(s) from the FTC, have awareness of activities under this Plan, including activation, deactivation, and scheduling of meetings. The Attorney General, the FTC Chair, or their delegates may attend Sub-Committee meetings and request to be apprised of any activities taken in accordance with activities under this Plan. DOJ or FTC Representatives may request and review any proposed action by the Sub-Committee or Sub-Committee Participants undertaken pursuant to this Plan, including the provision of data. If any DOJ or FTC Representative believes any actions proposed or taken are not consistent with relevant antitrust protections provided by the DPA, he or she shall provide warning and guidance to the Sub-Committee as soon as the potential issue is identified. If questions arise about the antitrust protections applicable to any particular action, FEMA may request DOJ, in consultation with the FTC, provide an opinion on the

legality of the action under relevant DPA antitrust protections.

XIV. Establishment of the Sub-Committees

This Plan establishes Sub-Committees to implement the Plan to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Drug Products, Drug Substances, and Associated Medical Devices to Respond to COVID–19 to provide the Federal Government and the Participants a forum to maximize the manufacture and efficient distribution of selected types of Drug Products, Drug Substances, and Associated Medical Devices and to create a prioritization protocol based upon identified types of Drug Product, Drug Substance, and Associated Medical Device End-Users and their demonstrated or projected requirements, and demonstrated or projected geographic and regional areas of need. The outcome should include a framework to expeditiously meet any Drug Product, Drug Substance, and Associated Medical Device needs in Exigent Circumstances anywhere in the Nation, and to ensure that actions to support Drug Product, Drug Substance, and Associated Medical Device stockpiling and reserves do not interfere with immediate requirements that would result in an unacceptable risk to healthcare providers or other potential Drug Product, Drug Substance, and Associated Medical Device recipients. A Sub-Committee Chairperson designated by the Chairperson will convene and preside over each Sub-Committee. Sub-Committees will not be used for contract negotiations or contract discussions between the Participants and the Federal Government; such negotiations or discussions will be in accordance with applicable federal contracting policies and procedures. However, this shall not limit any discussion within a Sub-Committee about the operational utilization of existing and potential contracts between the Participants and Representatives when seeking to align their use with overall manufacturing and distribution efforts consistent with this Plan.

Each Sub-Committee will consist of designated Representatives from FEMA, HHS, other federal agencies with equities in this Plan, and each Sub-Committee Participant. The Attorney General and Chair of the FTC, or their delegates, may also join each Sub-Committee and attend meetings at their discretion. Attendees may also be invited at the discretion of a Sub-Committee Chairperson as subject matter experts, to provide technical advice, or to represent other government agencies, but will not be considered part of the Sub-Committee.

To the extent necessary to respond to the Pandemic, only at the explicit direction of a Sub-Committee Chairperson, and subject to the provisions of Section V(B), Sub-Committee Members may be asked to provide technical advice, share information, help identify and validate places and resources of the greatest need, help project future manufacturing and distribution demands, assist in identifying and resolving the allocation of scarce resources amongst all necessary public and private sector domestic needs under Exigent Circumstances, and take any other necessary actions to maximize the timely manufacture and distribution of Drug Products, Drug Substances, and Associated Medical Devices as determined necessary by FEMA to respond to the Pandemic. A Sub-Committee Chairperson or his or her designee, at the Sub-Committee Chairperson's sole discretion, will make decisions on these issues in order to ensure the maximum efficiency and effectiveness in the use of Sub-Committee Member's resources. All Sub-Committee Participants will be invited to open Sub-Committee meetings. For selected Sub-Committee meetings, attendance may be limited to designated Sub-Committee Participants to meet specific operational requirements, as determined by FEMA.

Each Sub-Committee Chairperson shall notify the Attorney General, the Chair of the FTC, Representatives, and Participants of the time, place, and nature of each meeting and of the proposed agenda of each meeting to be held to carry out this Plan. Additionally, each Sub-Committee Chairperson shall provide for publication in the **Federal Register** of a notice of the time, place, and nature of each meeting. If a meeting is open, a **Federal Register** notice will be published reasonably in advance of the meeting. A Sub-Committee Chairman may restrict attendance at meetings only on the grounds outlined by 44 CFR 332.5(c)(1)–(3). If a meeting is closed, a **Federal Register** notice will be published within ten (10) days of the meeting and will include the reasons why the meeting is closed pursuant to 44 CFR 332.3(c)(2).

The Sub-Committee Chairperson shall establish the agenda for each meeting, be responsible for adherence to the agenda, and provide for a written summary or other record of each meeting and provide copies of transcripts or other records to FEMA, the Attorney General, the Chair of the FTC, and all Sub-Committee Participants. The Chairperson shall take necessary actions to protect from public disclosure any data discussed with or obtained from Sub-Committee Participants which a Sub-Committee Participant has identified as a trade secret or as privileged and confidential in accordance with DPA sections 708(h)(3) and 705(d), or which qualifies for withholding under 44 CFR 332.5.

XV. Application and Agreement

The Sub-Committee Participant identified below hereby agrees to join in the Federal Emergency Management Agency sponsored Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Drug Products, Drug Substances, and Associated Medical Devices under the Voluntary Agreement for the Manufacture and Distribution of Healthcare Resources Necessary to Respond to a Pandemic and to become a Participant in one or more Sub-Committees established by this Plan. This Plan will be published in the **Federal Register**. This Plan is authorized under section 708 of the Defense Production Act of 1950, as amended. Regulations governing the Voluntary Agreement for the Manufacture and Distribution of Healthcare Resources Necessary to Respond to a Pandemic and all subsequent Plans of Action at 44 CFR part 332. The applicant, as a Sub-Committee Participant, agrees to comply with the provisions of section 708 of the Defense Production Act of 1950, as amended, the regulations at 44 CFR part 332, and the terms of this Plan.

XVI. Assignment

No Sub-Committee Participant may assign or transfer this Plan, in whole or in part, or any protections, rights or obligations hereunder without the prior written consent of the Sub-Committee Chairperson. When requested, the Sub-Committee Chairperson will respond to written requests for consent within 10 (ten) business days of receipt.

_____

(Company name)

_____

(Name of authorized representative)

_____

(Signature of authorized representative)

_____

(Date)

_____

Administrator (Sponsor)

_____

(Date)

Text of the Plan of Action To Establish a National Strategy for the Manufacture, Allocation, and Distribution of Medical Devices To Respond to COVID–19 Implemented Under the Voluntary Agreement for the Manufacture and Distribution of Critical Healthcare Resources Necessary To Respond to a Pandemic

Plan of Action To Establish a National Strategy for the Manufacture, Allocation, and Distribution of Medical Devices To Respond to COVID–19 Implemented Under the Voluntary Agreement for the Manufacture and Distribution of Critical Healthcare Resources Necessary To Respond to a Pandemic

Preface

Pursuant to section 708 of the Defense Production Act of 1950 (DPA), as amended (50 U.S.C. 4558), the Federal Emergency Management Agency (FEMA) Administrator (Administrator), after consultation with the Secretary of the Department of Health and Human Services (HHS), the Attorney General of the United States (Attorney General), and the Chair of the Federal Trade Commission (FTC), developed a Voluntary Agreement for the Manufacture and Distribution of Critical Healthcare Resources Necessary to Respond to a Pandemic (Voluntary Agreement), 85 FR 50035 (August 17, 2020). The Voluntary Agreement, which operates through a series of Plans of Action, maximizes the manufacture and efficient distribution of Critical Healthcare Resources nationwide to respond to a pandemic by establishing unity of effort between Participants and the Federal Government for integrated coordination, planning, information sharing with FEMA, as authorized by FEMA, and allocation and distribution of Critical Healthcare Resources.

This document establishes a Plan of Action (Plan) to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Medical Devices to Respond to COVID–19. This Plan will be implemented under the Voluntary Agreement by several Sub-Committees.

(1) Sub-Committee to Define COVID–19 Medical Device Requirements,

(2) Sub-Committee for General Hospital Devices,

(3) Sub-Committee for Immunology Devices,

(4) Sub-Committee for Microbiology Devices,

(5) Sub-Committee for Pathology Devices, and

(6) Sub-Committee for Toxicology Devices.

The Sub-Committee to Define COVID–19 Medical Device Requirements will be formed first.

FEMA may establish additional Sub-Committees under this Plan, so long as:

(1) The Sub-Committee addresses one specific and well-defined category of Medical Device; and

(2) The Sub-Committee is recommended by the Sub-Committee to Define COVID–19 Medical Device Requirements.

The purpose of the Plan and the Sub-Committees is to maximize the manufacture and efficient distribution of selected types of Medical Devices and create a prioritization protocol for End-Users based upon their demonstrated or projected requirements including geographic and regional circumstances. The primary goal of the Plan is to create a mechanism to immediately meet exigent Medical Device requests anywhere in the Nation and to ensure that actions to support Medical Device stockpiling and reserves do not interfere with immediate requirements that would result in an unacceptable risk to healthcare providers or other potential Medical Device recipients. When the requirements of the Plan are met, it affords Sub-Committee Participants defenses to civil and criminal actions brought under the antitrust laws (or any similar law of any state) for actions taken within the scope of the Plan. The Plan is designed to foster a close working relationship among FEMA, HHS, and Sub-Committee Participants to address national defense needs through cooperative action under the direction and active supervision of FEMA.

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XVII. Purpose

A pandemic may present conditions that pose a direct threat to the national defense of the United States or its preparedness programs such that, pursuant to DPA section 708(c)(1), an agreement to collectively coordinate, plan, and collaborate for the manufacture and distribution of Medical Devices is necessary for the national defense. This Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Medical Devices to Respond to COVID–19 is established under the Voluntary Agreement and establishes six Sub-Committees to oversee and implement the Plan. The Plan and Sub-Committees will optimize the manufacture and the efficient distribution of selected types of Medical Devices and create a prioritization protocol for End-Users based upon their demonstrated or projected requirements.

XVIII. Authorities

Section 708, Defense Production Act (50 U.S.C. 4558); sections 402(2) & 501(b), Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121–5207); sections 503(b)(2)(B) & 504(a)(10) & (16) of the Homeland Security Act of 2002 (6 U.S.C. 313(b)(2)(B), 314(a)(10) & (16)); sections

201, 301, National Emergencies Act (50 U.S.C. 1601 *et seq.*); section 319, Public Health Service Act (42 U.S.C. 247d); Executive Order (E.O.) 13911, 85 FR 18403 (March 27, 2020); Prioritization and Allocation of Certain Scarce or Threatened Health and Medical Resources for Domestic Use, 85 FR 20195 (April 10, 2020). Pursuant to DPA section 708(f)(1)(A), the Administrator certifies that this Plan is necessary for the national defense.

XIX. General Provisions

S. Definitions

Administrator

The FEMA Administrator is the Sponsor of the Voluntary Agreement. Pursuant to a delegation or redelegation of the functions given to the President by DPA section 708, the Administrator proposes and provides for the development and carrying out of the Voluntary Agreement, including through the development and implementation of Plans of Action. The Administrator is responsible for carrying out all duties and responsibilities required by 50 U.S.C. 4558 and 44 CFR part 332 and for appointing one or more Chairpersons to manage and administer the Committee and all Sub-Committees formed to carry out the Voluntary Agreement.

Agreement

The Voluntary Agreement for the Manufacture and Distribution of Critical Healthcare Resources Necessary to Respond to a Pandemic (Voluntary Agreement).

Allocation

The process of determining and directing the relative distribution among one or more competing requests from End-Users for the same Medical Devices. Through the Allocation process, FEMA—with participation from Sub-Committee Participants—will assess the actual needs of End-Users and determine how to divide the available and projected supply of Medical Devices to minimize impacts to life, safety, and economic disruption associated with shortages of Medical Devices. Allocation will take place only under Exigent Circumstances. FEMA retains decision-making authority for all Allocation under this Plan.

Attendees

Subject matter experts, invited by the Chairperson or a Sub-Committee Chairperson to attend meetings authorized under the Voluntary Agreement or this Plan, to provide technical advice or to represent other government agencies or interested parties. Invitations to attendees will be extended as required for Committee or Sub-Committee meetings and deliberations.

Chairperson

FEMA senior executive(s), appointed by the Administrator, to chair the Committee for the Distribution of Healthcare Resources Necessary to Respond to a Pandemic (Committee). The Chairperson shall be responsible for the overall management and administration of the Committee, the Voluntary Agreement, and Plans of Action developed under the Voluntary Agreement while remaining under the supervision of the Administrator; shall initiate, or approve in advance, each meeting held to discuss problems, determine policies, recommend actions, and make decisions necessary to carry out the Voluntary Agreement; appoint one or more co-Chairpersons to chair the Committee, and otherwise shall carry out all duties and responsibilities assigned to him. With the approval of the Administrator, the Chairperson may create one or more Sub-Committees, and may appoint one or more Sub-Committee Chairpersons to chair the Sub-Committees, as appropriate.

Committee

Committee for the Distribution of Healthcare Resources Necessary to Respond to a Pandemic established under the Voluntary Agreement.

Competitively Sensitive Information

Competitively Sensitive Information that is shared pursuant to this Plan may include any Document or other tangible thing or oral transmission that contains financial, business, commercial, scientific, technical, economic, or engineering information or data, including, but not limited to

- financial statements and data,
- customer and supplier lists,
- price and other terms of sale to customers,
- sales records, projections and forecasts,
- inventory levels,
- capacity and capacity utilization,
- cost information,
- sourcing and procurement information,
- manufacturing and production information,
- delivery and shipping information,
- systems and data designs, and
- methods, techniques, processes, procedures, programs, codes, or similar information,

whether tangible or intangible, and regardless of the method of storage, compilation, or recordation, if the owner thereof has taken reasonable measures to protect the information from disclosure to the public or competitors. These measures may be evidenced by marking or labeling the items as ''competitively sensitive information'' during submission to FEMA or in the Participant's customary and existing treatment of such information (regardless of labeling).

All Competitively Sensitive Information provided by a Sub-Committee Participant as described herein is deemed Competitively Sensitive Information, except for Information that:

a. Is published or has been made publicly available at the time of disclosure by the Sub-Committee Participant;

b. was in the possession of, or was lawfully and readily available to, FEMA from another source at the time of disclosure without breaching any obligation of confidentiality applicable to the other source; or

c. was independently developed or acquired without reference to or reliance upon the Sub-Committee Participant's Competitively Sensitive Information;

Where information deemed Competitively Sensitive Information is required to be disclosed by law, regulation, or court order, the ''Competitively Sensitive'' (or substantially similar) label will continue to attach to all information and portion(s) of documents that are not made public through the required disclosure.

Document

Any information, on paper or in electronic/audio/visual format, including written, recorded, and graphic materials of every kind, in the possession, custody, or control of the Participant and used or shared in the course of participation in the Voluntary Agreement or a subsequent Plan of Action.

End-User

This includes all direct and ancillary medical support including, but not limited to, hospitals, independent healthcare providers, nursing homes, medical laboratories, dental care providers, independent physician offices, first responders, alternate care facilities and the general public that reasonably represents the totality of the nation's response to COVID–19. ''End-User'' may also include essential workers necessary to maintain or restore critical infrastructure operations, including but not limited to law

enforcement, education, food and agriculture, energy, water and wastewater, and public works personnel.

Exigent Circumstances

As determined by the Chairperson, the actual or forecasted shortage of a particular type or types of Medical Devices which likely cannot be fulfilled via usual market mechanisms for an acute, critical time period, and where immediate and substantial harm is projected to occur from lack of intervention.

General Hospital Devices

Refers to general hospital and personal use devices intended for human use that are in commercial distribution, as classified and described in 21 CFR 880.

Immunology Devices

Refers to immunology devices intended for human use that are in commercial distribution, as classified and described in 21 CFR 866.

Medical Device

Defined under Section 201(h) of the Food, Drug and Cosmetic Act (21 U.S.C. 321) as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

1. Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,

2. intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

3. intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term ''device'' does not include software functions excluded pursuant to section 520(o) of the Food, Drug and Cosmetic Act.

Microbiology Devices

Refers to microbiology devices intended for human use that are in commercial distribution, as classified and described in 21 CFR 866.

Pandemic

A Pandemic is defined as an epidemic that has spread to human populations across a large geographic area that is subject to one or more declarations under the National Emergencies Act, the Public Health Service Act, or the Robert T. Stafford Disaster Relief and Emergency Assistance Act, or if the Administrator determines that one or more declarations is likely to occur and the epidemic poses a direct threat to the national defense or its preparedness programs. For example, Coronavirus Disease 2019 (COVID–19).

Participant

An individual, partnership, corporation, association, or private organization, other than a federal agency, that has substantive capabilities, resources or expertise to carry out the purpose of the Voluntary Agreement, that has been specifically invited to participate in the Voluntary Agreement by the Chairperson, and that has applied and agreed to the terms of the Voluntary Agreement. ''Participant'' includes a corporate or non-corporate entity entering into the Voluntary Agreement and all subsidiaries and affiliates of that entity in which that entity has 50 percent or more control either by stock ownership, board majority, or otherwise. The Administrator may invite Participants to join the Voluntary Agreement at any time during its effective period.

Pathology Devices

Refers to pathology devices intended for human use that are in commercial distribution, as classified and described in 21 CFR 864.

Plan of Action (Plan)

This document. A documented method, pursuant to 50 U.S.C. 4558(b)(2), proposed by FEMA to implement a particular set of activities under the Voluntary Agreement, through a Sub-Committee focused on a particular Critical Healthcare Resource, or pandemic response workstream or functional area necessary for the national defense.

Plan of Action Agreement

A separate commitment made by Participants upon invitation and agreement to participate in a Plan of Action as part of one or more Sub-Committees. Completing the Plan of Action Agreement confers responsibilities on the Participant consistent with those articulated in the Plan of Action and affords Participants a defense against antitrust claims under section 708 for actions taken to develop or carry out the Plan and the appropriate Sub-Committee(s), as described in Section IV below.

Representatives

The representatives the Administrator identifies and invites to the Committee from FEMA, HHS, and other federal agencies with equities in this Plan, and empowered to speak on behalf of their agencies' interests. The Attorney General and the Chair of the FTC, or their delegates, may also attend any meeting as a Representative.

Sub-Committee

A body formed by the Administrator from select Participants to implement a Plan of Action.

Sub-Committee Chairperson

FEMA executive, appointed by the Chairperson, to chair a Sub-Committee to implement a Plan of Action. The Sub-Committee Chairperson shall be responsible for the overall management and administration of the Sub-Committee in furtherance of this Plan while remaining under the supervision of the Administrator and the Chairperson.

Sub-Committee Members

Collectively the Sub-Committee Chairperson(s), Representatives, and Sub-Committee Participants. Jointly responsible developing and executing this Plan.

Sub-Committee Participant

A subset of Participants of the Committee, that have been specifically invited to participate in a Sub-Committee by the Sub-Committee Chairperson, and that have applied and agreed to the terms of this Plan and signed the Plan of Action Agreement. The Sub-Committee Chairperson may invite Participants in the Committee to join a Sub-Committee as a Sub-Committee Participant at any time during the Plan's effective period.

Toxicology Devices

Refers to clinical toxicology devices intended for human use that are in commercial distribution, as classified and described in 21 CFR 862.

T. Plan of Action Participation

This Plan will be carried out by a subset of Participants in the Voluntary Agreement through several Sub-Committees:

(1) Sub-Committee to Define COVID–19 Medical Device Requirements,

(2) Sub-Committee for General Hospital Devices,

(3) Sub-Committee for Immunology Devices,

(4) Sub-Committee for Microbiology Devices,

(5) Sub-Committee for Pathology Devices, and

(6) Sub-Committee for Toxicology Devices

The Sub-Committee to Define COVID–19 Medical Device Requirements will be formed first.

FEMA may establish additional Sub-Committees under this Plan, so long as:

(1) The Sub-Committee addresses one specific and well-defined category of Medical Device; and

(2) The Sub-Committee is recommended by the Sub-Committee to Define COVID–19 Medical Device Requirements.

Each Sub-Committee will consist of the (1) Sub-Committee Chairperson(s), (2) Representatives from FEMA, HHS, the Department of Justice (DOJ), and other federal agencies with equities in this Plan, and (3) Sub-Committee Participants that have substantive capabilities, resources or expertise to carry out the purpose of this Plan and have signed the Plan of Action Agreement. The Chairperson shall invite Sub-Committee Participants who, in his or her determination, are reasonably representative of the appropriate industry or segment of such industry. Other Attendees—invited by the Sub-Committee Chairperson as subject matter experts to provide technical advice or to represent the interests of other government agencies or interested parties—may also participate in Sub-Committee meetings. The naming of these Sub-Committees does not commit the Administrator to creating them unless and until circumstances dictate.

U. Effective Date and Duration of Participation

This Plan is effective immediately upon satisfaction of the requirements of DPA section 708(f)(1). This Plan shall remain in effect until terminated in accordance with 44 CFR 332.4. It shall be effective for no more than five (5) years from August 17, 2020, when the requirements of DPA section 708(f)(1) were satisfied for the Voluntary Agreement, unless otherwise terminated pursuant to DPA section 708(h)(9) and 44 CFR 332.4 or extended as set forth in DPA section 708(f)(2). No action may take place under this Plan until it is activated, as described in Section III(E), below.

V. Withdrawal

Participation in the Plan is voluntary, as is the acceptance of most obligations under the Plan. Sub-Committee Participants may withdraw from this Plan or from an individual Sub-Committee at any point, subject to the fulfillment of obligations previously agreed upon by the Participant prior to the date of withdrawal. Note that the obligations outlined in V.B regarding information management and associated responsibilities apply once a party has shared or received information through a Sub-Committee, and remain in place after the party's withdrawal from the Sub-Committee or Plan. If a Sub-Committee Participant indicates an intent to withdraw from the Plan due to a modification or amendment of the Plan (described below), the Sub-Committee Participant will not be required to perform actions directed by that modification or amendment. *Withdrawal from the Plan will automatically trigger withdrawal from all Sub-Committees; however, a Participant may withdraw from a Sub-Committee without also withdrawing from the Plan or other Sub-Committees.* To withdraw from the Plan or from an individual Sub-Committee, a Participant must provide written notice to the Administrator at least fifteen (15) calendar days prior to the effective date of that Sub-Committee Participant's withdrawal specifying the scope of withdrawal. Following receipt of such notice, the Administrator will inform the other Sub-Committee Participants of the date and the scope of the withdrawal.

Upon the effective date of the withdrawal from the Plan, the Sub-Committee Participant must cease all activities under the Plan. Upon the effective date of the withdrawal from one or more Sub-Committee(s), the Sub-Committee Participant must cease all activities under the Plan that pertain to the withdrawn Sub-Committee(s).

W. Plan of Action Activation and Deactivation

The Administrator, in consultation with the Chairperson and Sub-Committee Chairperson, will invite a select group of Participants in the Voluntary Agreement to form the following Sub-Committees, beginning with the Sub-Committee to Define COVID–19 Medical Device Requirements, which will be responsible for implementing this Plan.

(1) Sub-Committee to Define COVID–19 Medical Device Requirements,

(2) Sub-Committee for General Hospital Devices,

(3) Sub-Committee for Immunology Devices,

(4) Sub-Committee for Microbiology Devices,

(5) Sub-Committee for Pathology Devices, and

(6) Sub-Committee for Toxicology Devices

FEMA may establish additional Sub-Committees under this Plan, so long as:

(1) The Sub-Committee addresses one specific and well-defined category of Medical Device; and

(2) The Sub-Committee is recommended by the Sub-Committee to Define COVID–19 Medical Device Requirements.

This Plan will be activated for each invited Participant when the Participant executes a Plan of Action Agreement, and a Participant may not participate in a Sub-Committee until the Plan of Action Agreement is executed. Participants will be invited to join this Plan at the discretion of the Chairperson or the Sponsor to the Voluntary Agreement. Participants will be further invited to attend specific meetings of one or more Sub-Committees at the discretion of the Chairperson.

X. Rules and Regulations

Sub-Committee Participants acknowledge and agree to comply with all provisions of DPA section 708, as amended, and regulations related thereto which are promulgated by FEMA, the Department of Homeland Security, HHS, the Attorney General, and the FTC. FEMA has promulgated standards and procedures pertaining to voluntary agreements in 44 CFR part 332. The Administrator shall inform Participants of new rules and regulations as they are issued.

Y. Modification and Amendment

The Administrator, after consultation with the Attorney General and the Chair of the FTC, may terminate or modify, in writing, this Plan at any time. The Attorney General, after consultation with the Chair of the FTC and the Administrator, may terminate or modify, in writing, this Plan at any time. Sub-Committee Participants may propose modifications or amendments to the Plan or to the Sub-Committees at any time.

Where possible, material modifications to the Plan or a Sub-Committee will be subject to a 30 calendar day delayed implementation and opportunity for notice and comment by Sub-Committee Participants to the Chairperson. This delayed implementation period may be shortened or eliminated if the Administrator deems it necessary. The Administrator shall inform Sub-Committee Participants of modifications or amendments to the Plan or to the Sub-Committees as they are proposed and issued.

The Administrator, after consultation with the Attorney General and the Chair of the FTC, may remove Sub-Committee Participants from the Plan or from a Sub-Committee at any time. The Attorney General, after consultation with the Chair of the FTC and the Administrator, may remove Sub-Committee Participants from this Plan or from a Sub-Committee at any time. If a Participant is removed from the Plan or from a Sub-Committee, the Participant may request written notice of the reasons for removal from the Chairperson, who shall provide such notice in a reasonable time period.

Z. Expenses

Participation in this Plan or in a Sub-Committee does not confer funds to Sub-Committee Participants, nor does it limit or prohibit any pre-existing source of funds. Unless otherwise specified, all expenses, administrative or otherwise, incurred by Sub-Committee Participants associated with participation in this Plan or a Sub-Committee shall be borne exclusively by the Sub-Committee Participants.

AA. Record Keeping

Each Sub-Committee Chairperson shall have primary responsibility for maintaining records in accordance with 44 CFR part 332 and shall be the official custodian of records related to carrying out this Plan. Each Sub-Committee Participant shall maintain for five years all minutes of meetings, transcripts, records, documents, and other data, including any communications with other Sub-Committee Participants or with any other member of the Sub-Committee, including drafts, related to the carrying out of this Plan or incorporating data or information received in the course of carrying out this Plan. Each Sub-Committee Participant agrees to produce to the Administrator, the Attorney General, and the Chair of the FTC upon request any item that this section requires the Participant to maintain. Any record maintained in accordance with 44 CFR part 332 shall be available for public inspection and copying, unless exempted on the grounds specified in 5 U.S.C. 552(b)(1), (3) or (4) or identified as privileged and confidential information in accordance with DPA section 705(d), and 44 CFR 332.5.

XX. Antitrust Defense

Under the provisions of DPA subsection 708(j), each Sub-Committee Participant in this Plan shall have available as a defense to any civil or criminal action brought for violation of the antitrust laws (or any similar law of any State) with respect to any action to develop or carry out this Plan, that such action was taken by the Sub-Committee Participant in the course of developing or carrying out this Plan, that the Sub-Committee Participant complied with the provisions of DPA section 708 and the rules promulgated thereunder, and that the Sub-Committee Participant acted in accordance with the terms of the Voluntary Agreement and this Plan. Except in the case of actions taken to develop this Plan, this defense shall be available only to the extent the Sub-Committee Participant asserting the defense demonstrates that the action was specified in, or was within the scope of, this Plan and within the scope of the appropriate Sub-Committee(s), including being taken at the direction and under the active supervision of FEMA.

This defense shall not apply to any actions taken after the termination of this Plan. Immediately upon modification of this Plan, no defense to antitrust claims under Section 708 shall be available to any subsequent action that is beyond the scope of the modified Plan. The Sub-Committee Participant asserting the defense bears the burden of proof to establish the elements of the defense. The defense shall not be available if the person against whom the defense is asserted shows that the action was taken for the purpose of violating the antitrust laws.

XXI. Terms and Conditions

As the sponsoring agency, FEMA will maintain oversight over Sub-Committee activities and direct and supervise actions taken to carry out this Plan, including by retaining decision-making authority over actions taken pursuant to the Plan to ensure such actions are necessary to address a direct threat to the national defense. The Attorney General and the Chair of the FTC will monitor activities of the Sub-Committees to ensure they execute their responsibilities in a manner consistent with this Plan and their actions have the least anticompetitive effects possible.

A. Plan of Action Execution

This Plan will be used to support the following objectives to respond to a Pandemic by maximizing the manufacture and efficient distribution of selected types of Medical Devices and creating a prioritization protocol for End-Users based upon their demonstrated or projected requirements and taking into account geographic and regional circumstances. Each Sub-Committee will undertake the following Objectives for the Medical Devices within its area of jurisdiction.

1. Objectives

(1) Optimize the timely production of sufficient quantities of Medical Devices to reduce loss of life and transmission of the COVID–19 virus.

(2) Ensure Medical Devices are distributed effectively across the whole community nationally based on risk.

(3) Balance restoration and maintenance of the nation's stockpile of Medical Devices with near-term requirements.

(4) Establish a process for FEMA Allocation of Medical Devices nationwide.

(5) Ensure ongoing competition in the manufacture and distribution of Medical Devices to the greatest extent possible under the DPA.

2. Actions

Sub-Committee Participants may be asked to support these objectives by taking the following specific actions:

(1) Assist the Chairperson in identifying which types of Medical Devices should be included within each Sub-Committee. Identification will be based upon each item's importance to the national response to COVID–19 and whether it can be reasonably inferred, based upon the best evidence available, that that current and projected supply measured against current and projected demand may not adequately meet the Medical Device requirements to all identified End-Users or regional or geographic areas of the country as result of measures taken to respond to COVID–19.

(2) Provide input to the Chairperson in creating a prioritized list of Medical Device End-Users by categories for each type of Medical Device identified by each Sub-Committee and ascertaining the relative demand and supply of Medical Devices among and within those End-User categories. Prioritization shall be decided by the Chairperson, based upon each item's importance, reflecting the consensus views of the Sub-Committee Members that it represents the most effective way to save lives and prevent the transmission of the COVID–19 virus. This list may be updated throughout the life of the Plan based upon either short term or long-term demands. These categories should be considered holistically in terms of the Whole-of-Nation response to COVID–19.

(3) Evaluate the domestic supply of Medical Devices and identify when the expansion of the domestic manufacture of Medical Devices may be necessary, as directed and decided by the Chairperson.

(4) Provide information, assist, and validate, as necessary as decided by the

Chairperson, demand projections for Medical Devices.

(5) Create a process for and collaborate in the evaluation of competing claims for Medical Devices from End-Users.

(6) Prepare a general strategy to accomplish the activities listed in V(A)(2)(7) below regarding activities in Exigent Circumstances consistent with the decisions made by the Chairperson.

(7) In Exigent Circumstances, with review and concurrence in all possible instances by DOJ in consultation with FTC:

- Facilitate maximum availability of Medical Devices to the nation or particular geographies by deconflicting overlapping demands from the collective Participants' customer base, as directed and decided by the Chairperson.
- Facilitate maximum availability of Medical Devices to the nation or particular geographies by deconflicting overlapping supply chain demands placed upon Members, as directed and decided by the Chairperson.
- Facilitate the efficient distribution of Medical Devices by deconflicting overlapping distribution chain activities of Members, as directed and decided by the Chairperson.
- Create a process for and collaborate in the Allocation of Medical Devices nationwide or in particular geographies consistent with the decisions made by the Chairperson.
- Create a process for and collaborate in meeting any other exigent requirements throughout the nation or particular geographies consistent with the overall strategy prepared by this Sub-Committee.

(8) Provide data and information necessary to validate the efforts of the Sub-Committee including the actual and planned amounts of Medical Devices to be distributed throughout the Nation, as determined by the Chairperson.

(9) Provide feedback to the Sub-Committee on the outcomes of the collective efforts of the Sub-Committee Members and any impediments or bottlenecks.

(10) Advise the Chairperson whether additional Participants or Attendees should be invited to join this Plan and Sub-Committee.

(11) Carry out other activities regarding Medical Devices as identified by Sub-Committees under this Plan as determined and directed by the Chairperson necessary to address the COVID–19 virus' direct threat to the national defense, where such activities have been reviewed and approved by DOJ and FTC and received concurrence from Sub-Committee members.

F. Information Management and Responsibilities

FEMA will request only that data and information from Sub-Committee Participants that is necessary to meet the objectives of the Plan and consistent with the scope of the relevant Sub-Committees. Upon signing a Plan of Action Agreement for this Plan, FEMA requests that Participants endeavor to cooperate with diligence and speed, and to the extent permissible under this Plan, and share with FEMA data and information necessary to meet the objectives of this Plan.

Sub-Committee Participants agree to share with FEMA the following data with diligence and speed, to the extent permissible under this Plan, and abide by the following guidelines, where feasible and consistent with the data that is owned by each Sub-Committee Participant:

(1) In general, Participants will not be asked to share Competitively Sensitive Information directly with other Participants.

(2) FEMA will only request direct sharing of Competitively Sensitive Information among Participants during Exigent Circumstances where there is a mission critical need or timeline such that sharing only through FEMA is impractical or threatens the outcome of the Plan or Sub-Committee action. Such requests, if made, will be only among Participants whose participation is necessary to meet the objectives of the Plan, will be limited in scope to the greatest extent possible, and will be shared only pursuant to safeguards subject to prior review and audit by DOJ and FTC. Direct sharing of Competitively Sensitive Information with other Participants will be limited in scope and circumstances to the greatest extent possible. Participants may not share Competitively Sensitive Information directly with other Participants unless specifically requested by FEMA, in consultation with DOJ and FTC. All Competitively Sensitive Information delivered to FEMA or to another Sub-Committee Participant shall be delivered by secure means, for example, password-protected or encrypted electronic files or drives with the password/key delivered by separate communication or method or via upload to an appropriately secure web portal as directed by FEMA. All data delivered to the web portal designated by FEMA is deemed to be Competitively Sensitive Information.

(3) To allow FEMA to identify and appropriately protect documents containing Competitively Sensitive Information by the Sub-Committee Participant providing the documents, the Sub-Committee Participant will make good faith efforts to designate any Competitively Sensitive Information by placing restrictive markings on documents and things considered to be competitively sensitive, the restrictive markings being sufficiently clear in wording and visibility to indicate the restricted nature of the data. The Sub-Committee Participant will identify Competitively Sensitive Information that is disclosed verbally by oral warning. Information designated as competitively sensitive will, to the extent allowed by law, be presumed to constitute confidential or privileged commercial or financial information, and be provided by the Sub-Committee Participant to FEMA with the expectation that it will be kept confidential by both parties, as such terms are understood in accordance with 5 U.S.C. 552(b)(4) of the Freedom of Information Act and federal judicial interpretations of this statute. FEMA agrees that to the extent any information designated as competitively sensitive by a Sub-Committee Participant is responsive to a request for disclosure under the Freedom of Information Act, FEMA will consult with the Sub-Committee Participant and afford the Participant ten (10) working days to object to any disclosure by FEMA.

(4) FEMA will make good faith efforts to appropriately recognize unmarked Documents containing Competitively Sensitive Information as Competitively Sensitive Information. However, FEMA cannot guarantee that all unmarked Documents will be recognized as being Competitively Sensitive Information and protected from disclosure to third parties. If the unmarked Documents have not been disclosed without restriction outside of FEMA, the Sub-Committee Participant may retroactively request to have appropriate designations placed on the Documents. If the unmarked Documents have been disclosed without restriction outside of FEMA, FEMA will, to the extent practicable, remove any requested information from public forums controlled by FEMA and will work promptly to request that a receiving party return or destroy disclosed unmarked Documents if requested by the Sub-Committee Participant.

(5) Competitively Sensitive Information may be used by FEMA, alone or in combination with additional information, including Documents and Competitively Sensitive Information received from third parties, to support FEMA's implementation of this Plan as determined by the Chairperson. In all situations, FEMA will aggregate and

anonymize Competitively Sensitive Information to the greatest extent possible to protect the interests retained by the owners of the data while still allowing the objectives of the Plan and Sub-Committee to be achieved. To the greatest extent possible, such aggregation will render the competitively sensitive nature of the Competitively Sensitive Information of the Sub-Committee Participant no longer recognizable in a commercially sensitive manner, and without sufficient information to enable, by inference or otherwise, attribution to Sub-Committee Participant or its affiliates (as clearly identified and disclosed to FEMA). Any disclosure of Competitively Sensitive Information by FEMA, within or outside a Sub-Committee, will be subject to review and approval by DOJ and FTC.

(6) Except as otherwise expressly permitted by applicable federal law, FEMA shall not disclose any Competitively Sensitive Information or use any Competitively Sensitive Information for any purpose other than in connection with the purposes of this Plan, and FEMA will not sell any Competitively Sensitive Information of any Sub-Committee Participant.

(7) Except as described below, FEMA may disclose Competitively Sensitive Information only to its employees, officers, directors, contractors, agents, and advisors (including attorneys, accountants, consultants, and financial advisors). Any individual with access to Competitively Sensitive Information will be expected to comply with the terms of this Plan.

a. *Information Sharing within the Sub-Committee:* FEMA may share Competitively Sensitive Information with Sub-Committee Participants and Federal Representatives of the Plan, and their respective employees, officers, directors, contractors, agents, and advisors (including attorneys, accountants, consultants, and financial advisors) where there is a need to know and where disclosure is reasonably necessary in furtherance of implementing the Plan. FEMA will aggregate and anonymize data prior to sharing with the Sub-Committee Participants to the greatest extent possible while still allowing the objectives of the Plan to be achieved, and will not share data—particularly to competitors of the submitter—prior to consultation with and approval by the DOJ and FTC.

i. Sub-Committee Participants, when providing Competitively Sensitive Information to FEMA, may request that this Information not be shared with other Sub-Committee Participants. Where these requests are made in good faith and are reasonable in nature, FEMA will respect these requests to the greatest extent possible and will consult the owner of the data prior to any release made to Sub-Committee Participants.

b. *Restricted Reports.* FEMA may communicate Competitively Sensitive Information to appropriate government officials through Restricted Reports. The information contained in Restricted Reports shall be aggregated and anonymized to the greatest extent possible, while recognizing that these officials may need a certain amount of granularity and specificity of information to appropriately respond to COVID–19. FEMA will aim to aggregate data to the County level, and will not share Restricted Reports prior to consultation and approval from the DOJ and FTC. FEMA may disclose Restricted Reports to relevant White House and Administration officials and State Governors, and their respective employees, officers, directors, contractors, agents, and advisors (including attorneys, accountants, consultants, and financial advisors) who have a need to know and to whom such disclosure is reasonably necessary solely in furtherance of the implementation of this Plan. FEMA shall take appropriate action (by instructions, agreement, or otherwise) to ensure that receiving parties comply with all data-sharing confidentiality and obligations under this Plan as if such persons or entities had been parties to this Plan.

c. *Public Reports.* FEMA may share information with the public through Public Reports. Data contained in Public Reports shall be fully aggregated and anonymized. Public Reports shall be aggregated to at least a state level and may be publicly disclosed after consultation and approval from the DOJ and FTC.

(8) Where possible and not obviated by Exigent Circumstances, FEMA will notify Sub-Committee Participants prior to the release of any Competitively Sensitive Information that has not been fully aggregated and anonymized. In consultation with DOJ and FTC, FEMA will consider any good-faith requests made by Sub-Committee members to hold the release of data or requests for further aggregation or anonymization. In general, FEMA will not provide notification prior to the release of *Public Reports,* under the presumption that the data in these reports has already been fully anonymized and de-identified.

(9) Any party receiving Competitively Sensitive Information through this Plan shall use such information solely for the purposes outlined in the Plan and take steps, such as imposing previously approved firewalls or tracking usage, to prevent misuse of the information. Disclosure and use of Competitively Sensitive Information will be limited to the greatest extent possible, and any party receiving Competitively Sensitive Information shall follow the procedures outlined in paragraph 7 above.

(10) At the conclusion of a Participant's involvement in a Plan—due to the deactivation of the Plan or due to the Participant's withdrawal or removal—each Participant will be requested to sequester any and all Competitively Sensitive Information received through participation in the Plan. This sequestration shall include the deletion of all Competitively Sensitive Information unless required to be kept pursuant to the Record Keeping requirements as described *supra,* Section I, 44 CFR part 332, or any other provision of law.

G. Oversight

Each Sub-Committee Chairperson is responsible for ensuring that the Attorney General, or suitable delegate(s) from the DOJ, and the FTC Chair, or suitable delegate(s) from the FTC, have awareness of activities under this Plan, including activation, deactivation, and scheduling of meetings. The Attorney General, the FTC Chair, or their delegates may attend Sub-Committee meetings and request to be apprised of any activities taken in accordance with activities under this Plan. DOJ or FTC Representatives may request and review any proposed action by the Sub-Committee or Sub-Committee Participants undertaken pursuant to this Plan, including the provision of data. If any DOJ or FTC Representative believes any actions proposed or taken are not consistent with relevant antitrust protections provided by the DPA, he or she shall provide warning and guidance to the Sub-Committee as soon as the potential issue is identified. If questions arise about the antitrust protections applicable to any particular action, FEMA may request DOJ, in consultation with the FTC, provide an opinion on the legality of the action under relevant DPA antitrust protections.

XXII. Establishment of the Sub-Committees

This Plan establishes Sub-Committees to implement the Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Medical Devices Critical to COVID–19 Response to provide the Federal Government and the Participants a forum to maximize the manufacture and efficient distribution

of selected types of Medical Devices and to create a prioritization protocol based upon identified types of Medical Device End-Users and their demonstrated or projected requirements, and demonstrated or projected geographic and regional areas of need. The outcome should include a framework to expeditiously meet any Medical Device needs in Exigent Circumstances anywhere in the Nation, and to ensure that actions to support Medical Device stockpiling and reserves do not interfere with immediate requirements that would result in an unacceptable risk to healthcare providers or other potential Medical Device recipients. A Sub-Committee Chairperson designated by the Chairperson will convene and preside over each Sub-Committee. Sub-Committees will not be used for contract negotiations or contract discussions between the Participants and the Federal Government; such negotiations or discussions will be in accordance with applicable federal contracting policies and procedures. However, this shall not limit any discussion within a Sub-Committee about the operational utilization of existing and potential contracts between the Participants and Representatives when seeking to align their use with overall manufacturing and distribution efforts consistent with this Plan.

Each Sub-Committee will consist of designated Representatives from FEMA, HHS, other federal agencies with equities in this Plan, and each Sub-Committee Participant. The Attorney General and Chair of the FTC, or their delegates, may also join each Sub-Committee and attend meetings at their discretion. Attendees may also be invited at the discretion of a Sub-Committee Chairperson as subject matter experts, to provide technical advice, or to represent other government agencies, but will not be considered part of the Sub-Committee.

To the extent necessary to respond to the Pandemic, only at the explicit direction of a Sub-Committee Chairperson, and subject to the provisions of Section V(B), Sub-Committee Members may be asked to provide technical advice, share information, help identify and validate places and resources of the greatest need, help project future manufacturing and distribution demands, assist in identifying and resolving the allocation of scarce resources amongst all necessary public and private sector domestic needs under Exigent Circumstances, and take any other necessary actions to maximize the timely manufacture and distribution of Medical Devices as determined necessary by FEMA to respond to the Pandemic. A Sub-Committee Chairperson or his or her designee, at the Sub-Committee Chairperson's sole discretion, will make decisions on these issues in order to ensure the maximum efficiency and effectiveness in the use of Sub-Committee Member's resources. All Sub-Committee Participants will be invited to open Sub-Committee meetings. For selected Sub-Committee meetings, attendance may be limited to designated Sub-Committee Participants to meet specific operational requirements, as determined by FEMA.

Each Sub-Committee Chairperson shall notify the Attorney General, the Chair of the FTC, Representatives, and Participants of the time, place, and nature of each meeting and of the proposed agenda of each meeting to be held to carry out this Plan. Additionally, each Sub-Committee Chairperson shall provide for publication in the **Federal Register** of a notice of the time, place, and nature of each meeting. If a meeting is open, a **Federal Register** notice will be published reasonably in advance of the meeting. A Sub-Committee Chairman may restrict attendance at meetings only on the grounds outlined by 44 CFR 332.5(c)(1)–(3). If a meeting is closed, a **Federal Register** notice will be published within ten (10) days of the meeting and will include the reasons why the meeting is closed pursuant to 44 CFR 332.3(c)(2).

The Sub-Committee Chairperson shall establish the agenda for each meeting, be responsible for adherence to the agenda, and provide for a written summary or other record of each meeting and provide copies of transcripts or other records to FEMA, the Attorney General, the Chair of the FTC, and all Sub-Committee Participants. The Chairperson shall take necessary actions to protect from public disclosure any data discussed with or obtained from Sub-Committee Participants which a Sub-Committee Participant has identified as a trade secret or as privileged and confidential in accordance with DPA sections 708(h)(3) and 705(d), or which qualifies for withholding under 44 CFR 332.5.

XXIII. Application and Agreement

The Sub-Committee Participant identified below hereby agrees to join in the Federal Emergency Management Agency sponsored Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Medical Devices to Respond to COVID–19 under the Voluntary Agreement for the Manufacture and Distribution of Healthcare Resources Necessary to Respond to a Pandemic and to become a Participant in one or more Sub-Committees established by this Plan. This Plan will be published in the **Federal Register**. This Plan is authorized under section 708 of the Defense Production Act of 1950, as amended. Regulations governing the Voluntary Agreement for the Manufacture and Distribution of Healthcare Resources Necessary to Respond to a Pandemic and all subsequent Plans of Action at 44 CFR part 332. The applicant, as a Sub-Committee Participant, agrees to comply with the provisions of section 708 of the Defense Production Act of 1950, as amended, the regulations at 44 CFR part 332, and the terms of this Plan.

XXIV. Assignment

No Sub-Committee Participant may assign or transfer this Plan, in whole or in part, or any protections, rights or obligations hereunder without the prior written consent of the Sub-Committee Chairperson. When requested, the Sub-Committee Chairperson will respond to written requests for consent within 10 (ten) business days of receipt.

_____

(Company name)

_____

(Name of authorized representative)

_____

(Signature of authorized representative)

_____

(Date)

_____

Administrator (Sponsor)

_____

(Date)

Text of the Plan of Action To Establish a National Strategy for the Manufacture, Allocation, and Distribution of Medical Gases To Respond to COVID–19 Implemented Under the Voluntary Agreement for the Manufacture and Distribution of Critical Healthcare Resources Necessary To Respond to a Pandemic

Plan of Action To Establish a National Strategy for the Manufacture, Allocation, and Distribution of Medical Gases To Respond to COVID–19 Implemented Under the Voluntary Agreement for the Manufacture and Distribution of Critical Healthcare Resources Necessary To Respond to a Pandemic

Preface

Pursuant to section 708 of the Defense Production Act of 1950 (DPA), as amended (50 U.S.C. 4558), the Federal Emergency Management Agency (FEMA) Administrator (Administrator), after consultation with the Secretary of

the Department of Health and Human Services (HHS), the Attorney General of the United States (Attorney General), and the Chair of the Federal Trade Commission (FTC), developed a Voluntary Agreement for the Manufacture and Distribution of Critical Healthcare Resources Necessary to Respond to a Pandemic (Voluntary Agreement), 85 FR 50035 (August 17, 2020). The Voluntary Agreement, which operates through a series of Plans of Action, maximizes the manufacture and efficient distribution of Critical Healthcare Resources nationwide to respond to a pandemic by establishing unity of effort between Participants and the Federal Government for integrated coordination, planning, information sharing with FEMA, as authorized by FEMA, and allocation and distribution of Critical Healthcare Resources.

This document establishes a Plan of Action (Plan) to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Medical Gases to Respond to COVID–19. This Plan will be implemented under the Voluntary Agreement by several Sub-Committees.

(1) Sub-Committee to Define COVID–19 Medical Gas Requirements,

(2) Sub-Committee for Oxygen,

(3) Sub-Committee for Nitrous Oxide,

(4) Sub-Committee for Carbon Dioxide,

(5) Sub-Committee for Heliox,

(6) Sub-Committee for Nitrogen (Medical Liquid Nitrogen), and

(7) Sub-Committee for Medical Air.

The Sub-Committee to Define COVID–19 Medical Gas Requirements will be formed first.

FEMA may establish additional Sub-Committees under this Plan, so long as:

(1) The Sub-Committee addresses one specific and well-defined category of Medical Gases; and

(2) The Sub-Committee is recommended by the Sub-Committee to Define COVID–19 Medical Gas Requirements.

The purpose of the Plan and the Sub-Committees is to maximize the manufacture and efficient distribution of selected types of Medical Gases and create a prioritization protocol for End-Users based upon their demonstrated or projected requirements including geographic and regional circumstances. The primary goal of the Plan is to create a mechanism to immediately meet exigent Medical Gas requests anywhere in the Nation and to ensure that actions to support Medical Gas stockpiling and reserves do not interfere with immediate requirements that would result in an unacceptable risk to healthcare providers or other potential Medical Gas recipients. When the requirements of the Plan are met, it affords Sub-Committee Participants defenses to civil and criminal actions brought under the antitrust laws (or any similar law of any state) for actions taken within the scope of the Plan. The Plan is designed to foster a close working relationship among FEMA, HHS, and Sub-Committee Participants to address national defense needs through cooperative action under the direction and active supervision of FEMA.

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XXV. Purpose

A pandemic may present conditions that pose a direct threat to the national defense of the United States or its preparedness programs such that, pursuant to DPA section 708(c)(1), an agreement to collectively coordinate, plan, and collaborate for the manufacture and distribution of Medical Gases is necessary for the national defense. This Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Medical Gases to Respond to COVID–19 is established under the Voluntary Agreement and establishes seven Sub-Committees to oversee and implement the Plan. The Plan and Sub-Committees will optimize the manufacture and the efficient distribution of selected types of Medical Gases and create a prioritization protocol for End-Users based upon their demonstrated or projected requirements.

XXVI. Authorities

Section 708, Defense Production Act (50 U.S.C. 4558); sections 402(2) & 501(b), Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121–5207); sections 503(b)(2)(B) & 504(a)(10) & (16) of the Homeland Security Act of 2002 (6 U.S.C. 313(b)(2)(B), 314(a)(10) & (16)); sections 201, 301, National Emergencies Act (50 U.S.C. 1601 *et seq.*); section 319, Public Health Service Act (42 U.S.C. 247d); Executive Order (E.O.) 13911, 85 FR 18403 (March 27, 2020); Prioritization and Allocation of Certain Scarce or Threatened Health and Medical Resources for Domestic Use, 85 FR 20195 (April 10, 2020). Pursuant to DPA section 708(f)(1)(A), the Administrator certifies that this Plan is necessary for the national defense.

XXVII. General Provisions

BB. Definitions

Administrator

The FEMA Administrator is the Sponsor of the Voluntary Agreement. Pursuant to a delegation or redelegation of the functions given to the President by DPA section 708, the Administrator proposes and provides for the development and carrying out of the Voluntary Agreement, including through the development and implementation of Plans of Action. The Administrator is responsible for carrying out all duties and responsibilities required by 50 U.S.C. 4558 and 44 CFR part 332 and for

appointing one or more Chairpersons to manage and administer the Committee and all Sub-Committees formed to carry out the Voluntary Agreement.

Agreement

The Voluntary Agreement for the Manufacture and Distribution of Critical Healthcare Resources Necessary to Respond to a Pandemic (Voluntary Agreement).

Allocation

The process of determining and directing the relative distribution among one or more competing requests from End-Users for the same Medical Gases. Through the Allocation process, FEMA—with participation from Sub-Committee Participants—will assess the actual needs of End-Users and determine how to divide the available and projected supply of Medical Gases to minimize impacts to life, safety, and economic disruption associated with shortages of Medical Gases. Allocation will take place only under Exigent Circumstances. FEMA retains decision-making authority for all Allocation under this Plan.

Attendees

Subject matter experts, invited by the Chairperson or a Sub-Committee Chairperson to attend meetings authorized under the Voluntary Agreement or this Plan, to provide technical advice or to represent other government agencies or interested parties. Invitations to attendees will be extended as required for Committee or Sub-Committee meetings and deliberations.

Chairperson

FEMA senior executive(s), appointed by the Administrator, to chair the Committee for the Distribution of Healthcare Resources Necessary to Respond to a Pandemic (Committee). The Chairperson shall be responsible for the overall management and administration of the Committee, the Voluntary Agreement, and Plans of Action developed under the Voluntary Agreement while remaining under the supervision of the Administrator; shall initiate, or approve in advance, each meeting held to discuss problems, determine policies, recommend actions, and make decisions necessary to carry out the Voluntary Agreement; appoint one or more co-Chairpersons to chair the Committee, and otherwise shall carry out all duties and responsibilities assigned to him. With the approval of the Administrator, the Chairperson may create one or more Sub-Committees, and may appoint one or more Sub-Committee Chairpersons to chair the Sub-Committees, as appropriate.

Committee

Committee for the Distribution of Healthcare Resources Necessary to Respond to a Pandemic established under the Voluntary Agreement.

Competitively Sensitive Information

Competitively Sensitive Information that is shared pursuant to this Plan may include any Document or other tangible thing or oral transmission that contains financial, business, commercial, scientific, technical, economic, or engineering information or data, including, but not limited to

- financial statements and data,
- customer and supplier lists,
- price and other terms of sale to customers,
- sales records, projections and forecasts,
- inventory levels,
- capacity and capacity utilization,
- cost information,
- sourcing and procurement information,
- manufacturing and production information,
- delivery and shipping information,
- systems and data designs, and
- methods, techniques, processes, procedures, programs, codes, or similar information,

whether tangible or intangible, and regardless of the method of storage, compilation, or recordation, if the owner thereof has taken reasonable measures to protect the information from disclosure to the public or competitors. These measures may be evidenced by marking or labeling the items as ''competitively sensitive information'' during submission to FEMA or in the Participant's customary and existing treatment of such information (regardless of labeling).

All Competitively Sensitive Information provided by a Sub-Committee Participant as described herein is deemed Competitively Sensitive Information, except for Information that:

a. Is published or has been made publicly available at the time of disclosure by the Sub-Committee Participant;

b. was in the possession of, or was lawfully and readily available to, FEMA from another source at the time of disclosure without breaching any obligation of confidentiality applicable to the other source; or

c. was independently developed or acquired without reference to or reliance upon the Sub-Committee Participant's Competitively Sensitive Information;

Where information deemed Competitively Sensitive Information is required to be disclosed by law, regulation, or court order, the ''Competitively Sensitive'' (or substantially similar) label will continue to attach to all information and portion(s) of documents that are not made public through the required disclosure.

Document

Any information, on paper or in electronic/audio/visual format, including written, recorded, and graphic materials of every kind, in the possession, custody, or control of the Participant and used or shared in the course of participation in the Voluntary Agreement or a subsequent Plan of Action.

End-User

This includes all direct and ancillary medical support including, but not limited to, hospitals, independent healthcare providers, nursing homes, medical laboratories, dental care providers, independent physician offices, first responders, alternate care facilities and the general public that reasonably represents the totality of the nation's response to COVID–19.

Exigent Circumstances

As determined by the Chairperson, the actual or forecasted shortage of a particular type or types of Medical Gases which likely cannot be fulfilled via usual market mechanisms for an acute, critical time period, and where immediate and substantial harm is projected to occur from lack of intervention.

Medical Gases

Defined under Section 360ddd of the Food, Drug and Cosmetic Act (21 U.S.C. 360ddd) as a drug that is manufactured or stored in a liquefied, nonliquified, or cryogenic state, and administered as a gas. Medical Gases include, but are not limited to, Oxygen, Nitrogen, Nitrous oxide, Carbon dioxide, Helium, Carbon monoxide, and Medical air, so long as such gases meet the Standards established by the United States Pharmacopeia and the National Formulary (USP–NF).

Pandemic

A Pandemic is defined as an epidemic that has spread to human populations across a large geographic area that is subject to one or more declarations under the National Emergencies Act, the Public Health Service Act, or the Robert

T. Stafford Disaster Relief and Emergency Assistance Act, or if the Administrator determines that one or more declarations is likely to occur and the epidemic poses a direct threat to the national defense or its preparedness programs. For example, Coronavirus Disease 2019 (COVID–19).

Participant

An individual, partnership, corporation, association, or private organization, other than a federal agency, that has substantive capabilities, resources or expertise to carry out the purpose of the Voluntary Agreement, that has been specifically invited to participate in the Voluntary Agreement by the Chairperson, and that has applied and agreed to the terms of the Voluntary Agreement. ''Participant'' includes a corporate or non-corporate entity entering into the Voluntary Agreement and all subsidiaries and affiliates of that entity in which that entity has 50 percent or more control either by stock ownership, board majority, or otherwise. The Administrator may invite Participants to join the Voluntary Agreement at any time during its effective period.

Plan of Action (Plan)

This document. A documented method, pursuant to 50 U.S.C. 4558(b)(2), proposed by FEMA to implement a particular set of activities under the Voluntary Agreement, through a Sub-Committee focused on a particular Critical Healthcare Resource, or pandemic response workstream or functional area necessary for the national defense.

Plan of Action Agreement

A separate commitment made by Participants upon invitation and agreement to participate in a Plan of Action as part of one or more Sub-Committees. Completing the Plan of Action Agreement confers responsibilities on the Participant consistent with those articulated in the Plan of Action and affords Participants a defense against antitrust claims under section 708 for actions taken to develop or carry out the Plan of Action and the appropriate Sub-Committee(s), as described in Section IV below.

Representatives

The representatives the Administrator identifies and invites to the Committee from FEMA, HHS, and other federal agencies with equities in this Plan, and empowered to speak on behalf of their agencies' interests. The Attorney General and the Chair of the FTC, or their delegates, may also attend any meeting as a Representative.

Sub-Committee

A body formed by the Administrator from select Participants to implement a Plan of Action.

Sub-Committee Chairperson

FEMA executive, appointed by the Chairperson, to chair a Sub-Committee to implement a Plan of Action. The Sub-Committee Chairperson shall be responsible for the overall management and administration of the Sub-Committee in furtherance of this Plan while remaining under the supervision of the Administrator and the Chairperson.

Sub-Committee Members

Collectively the Sub-Committee Chairperson(s), Representatives, and Sub-Committee Participants. Jointly responsible developing and executing this Plan.

Sub-Committee Participant

A subset of Participants of the Committee, that have been specifically invited to participate in a Sub-Committee by the Sub-Committee Chairperson, and that have applied and agreed to the terms of this Plan and signed the Plan of Action Agreement. The Sub-Committee Chairperson may invite Participants in the Committee to join a Sub-Committee as a Sub-Committee Participant at any time during the Plan's effective period.

CC. Plan of Action Participation

This Plan will be carried out by a subset of Participants in the Voluntary Agreement through several Sub-Committees:

(1) Sub-Committee to Define COVID–19 Medical Gas Requirements,
(2) Sub-Committee for Oxygen,
(3) Sub-Committee for Nitrous Oxide,
(4) Sub-Committee for Carbon Dioxide,
(5) Sub-Committee for Heliox,
(6) Sub-Committee for Nitrogen (Medical Liquid Nitrogen), and
(7) Sub-Committee for Medical Air.

The Sub-Committee to Define COVID–19 Medical Gas Requirements will be formed first. FEMA may establish additional Sub-Committees under this Plan, so long as:

(1) The Sub-Committee addresses one specific and well-defined category of Medical Gases; and

(2) The Sub-Committee is recommended by the Sub-Committee to Define COVID–19 Medical Gas Requirements.

Each Sub-Committee will consist of the (1) Sub-Committee Chairperson(s), (2) Representatives from FEMA, HHS, the Department of Justice (DOJ), and other federal agencies with equities in this Plan, and (3) Sub-Committee Participants that have substantive capabilities, resources or expertise to carry out the purpose of this Plan and have signed the Plan of Action Agreement. The Chairperson shall invite Sub-Committee Participants who, in his or her determination, are reasonably representative of the appropriate industry or segment of such industry. Other Attendees—invited by the Sub-Committee Chairperson as subject matter experts to provide technical advice or to represent the interests of other government agencies or interested parties—may also participate in Sub-Committee meetings. The naming of these Sub-Committees does not commit the Administrator to creating them unless and until circumstances dictate.

DD. Effective Date and Duration of Participation

This Plan is effective immediately upon satisfaction of the requirements of DPA section 708(f)(1). This Plan shall remain in effect until terminated in accordance with 44 CFR 332.4. It shall be effective for no more than five (5) years from August 17, 2020, when the requirements of DPA section 708(f)(1) were satisfied for the Voluntary Agreement, unless otherwise terminated pursuant to DPA section 708(h)(9) and 44 CFR 332.4 or extended as set forth in DPA section 708(f)(2). No action may take place under this Plan until it is activated, as described in Section III(E), below.

EE. Withdrawal

Participation in the Plan is voluntary, as is the acceptance of most obligations under the Plan. Sub-Committee Participants may withdraw from this Plan or from an individual Sub-Committee at any point, subject to the fulfillment of obligations previously agreed upon by the Participant prior to the date of withdrawal. Note that the obligations outlined in V.B regarding information management and associated responsibilities apply once a party has shared or received information through a Sub-Committee, and remain in place after the party's withdrawal from the Sub-Committee or Plan. If a Sub-Committee Participant indicates an intent to withdraw from the Plan due to a modification or amendment of the Plan (described below), the Sub-Committee Participant will not be required to perform actions directed by that modification or amendment. *Withdrawal from the Plan will automatically trigger withdrawal from*

all Sub-Committees; however, a Participant may withdraw from a Sub-Committee without also withdrawing from the Plan or other Sub-Committees. To withdraw from the Plan or from an individual Sub-Committee, a Participant must provide written notice to the Administrator at least fifteen (15) calendar days prior to the effective date of that Sub-Committee Participant's withdrawal specifying the scope of withdrawal. Following receipt of such notice, the Administrator will inform the other Sub-Committee Participants of the date and the scope of the withdrawal.

Upon the effective date of the withdrawal from the Plan, the Sub-Committee Participant must cease all activities under the Plan. Upon the effective date of the withdrawal from one or more Sub-Committee(s), the Sub-Committee Participant must cease all activities under the Plan that pertain to the withdrawn Sub-Committee(s).

FF. Plan of Action Activation and Deactivation

The Administrator, in consultation with the Chairperson and Sub-Committee Chairperson, will invite a select group of Participants in the Voluntary Agreement to form the following Sub-Committees, beginning with the Sub-Committee to Define COVID–19 Medical Gas Requirements, which will be responsible for implementing this Plan.

(1) Sub-Committee to Define COVID–19 Medical Gas Requirements,

(2) Sub-Committee for Oxygen,

(3) Sub-Committee for Nitrous Oxide,

(4) Sub-Committee for Carbon Dioxide,

(5) Sub-Committee for Heliox,

(6) Sub-Committee for Nitrogen (Medical Liquid Nitrogen), and

(7) Sub-Committee for Medical Air.

FEMA may establish additional Sub-Committees under this Plan, so long as:

(1) The Sub-Committee addresses one specific and well-defined category of Medical Gases; and

(2) The Sub-Committee is recommended by the Sub-Committee to Define COVID–19 Medical Gas Requirements.

This Plan will be activated for each invited Participant when the Participant executes a Plan of Action Agreement, and a Participant may not participate in a Sub-Committee until the Plan of Action Agreement is executed. Participants will be invited to join this Plan at the discretion of the Chairperson or the Sponsor to the Voluntary Agreement. Participants will be further invited to attend specific meetings of one or more Sub-Committees at the discretion of the Chairperson.

GG. Rules and Regulations

Sub-Committee Participants acknowledge and agree to comply with all provisions of DPA section 708, as amended, and regulations related thereto which are promulgated by FEMA, the Department of Homeland Security, HHS, the Attorney General, and the FTC. FEMA has promulgated standards and procedures pertaining to voluntary agreements in 44 CFR part 332. The Administrator shall inform Participants of new rules and regulations as they are issued.

HH. Modification and Amendment

The Administrator, after consultation with the Attorney General and the Chair of the FTC, may terminate or modify, in writing, this Plan at any time. The Attorney General, after consultation with the Chair of the FTC and the Administrator, may terminate or modify, in writing, this Plan at any time. Sub-Committee Participants may propose modifications or amendments to the Plan or to the Sub-Committees at any time.

Where possible, material modifications to the Plan or a Sub-Committee will be subject to a 30 calendar day delayed implementation and opportunity for notice and comment by Sub-Committee Participants to the Chairperson. This delayed implementation period may be shortened or eliminated if the Administrator deems it necessary. The Administrator shall inform Sub-Committee Participants of modifications or amendments to the Plan or to the Sub-Committees as they are proposed and issued.

The Administrator, after consultation with the Attorney General and the Chair of the FTC, may remove Sub-Committee Participants from the Plan or from a Sub-Committee at any time. The Attorney General, after consultation with the Chair of the FTC and the Administrator, may remove Sub-Committee Participants from this Plan or from a Sub-Committee at any time. If a Participant is removed from the Plan or from a Sub-Committee, the Participant may request written notice of the reasons for removal from the Chairperson, who shall provide such notice in a reasonable time period.

II. Expenses

Participation in this Plan or in a Sub-Committee does not confer funds to Sub-Committee Participants, nor does it limit or prohibit any pre-existing source of funds. Unless otherwise specified, all expenses, administrative or otherwise, incurred by Sub-Committee Participants associated with participation in this Plan or a Sub-Committee shall be borne exclusively by the Sub-Committee Participants.

JJ. Record Keeping

Each Sub-Committee Chairperson shall have primary responsibility for maintaining records in accordance with 44 CFR part 332 and shall be the official custodian of records related to carrying out this Plan. Each Sub-Committee Participant shall maintain for five years all minutes of meetings, transcripts, records, documents, and other data, including any communications with other Sub-Committee Participants or with any other member of the Sub-Committee, including drafts, related to the carrying out of this Plan or incorporating data or information received in the course of carrying out this Plan. Each Sub-Committee Participant agrees to produce to the Administrator, the Attorney General, and the Chair of the FTC upon request any item that this section requires the Participant to maintain. Any record maintained in accordance with 44 CFR part 332 shall be available for public inspection and copying, unless exempted on the grounds specified in 5 U.S.C. 552(b)(1), (3) or (4) or identified as privileged and confidential information in accordance with DPA section 705(d), and 44 CFR 332.5.

XXVIII. Antitrust Defense

Under the provisions of DPA subsection 708(j), each Sub-Committee Participant in this Plan shall have available as a defense to any civil or criminal action brought for violation of the antitrust laws (or any similar law of any State) with respect to any action to develop or carry out this Plan, that such action was taken by the Sub-Committee Participant in the course of developing or carrying out this Plan, that the Sub-Committee Participant complied with the provisions of DPA section 708 and the rules promulgated thereunder, and that the Sub-Committee Participant acted in accordance with the terms of the Voluntary Agreement and this Plan. Except in the case of actions taken to develop this Plan, this defense shall be available only to the extent the Sub-Committee Participant asserting the defense demonstrates that the action was specified in, or was within the scope of, this Plan and within the scope of the appropriate Sub-Committee(s), including being taken at the direction and under the active supervision of FEMA.

This defense shall not apply to any actions taken after the termination of this Plan. Immediately upon modification of this Plan, no defense to antitrust claims under Section 708 shall be available to any subsequent action that is beyond the scope of the modified Plan. The Sub-Committee Participant asserting the defense bears the burden of proof to establish the elements of the defense. The defense shall not be available if the person against whom the defense is asserted shows that the action was taken for the purpose of violating the antitrust laws.

XXIX. Terms and Conditions

As the sponsoring agency, FEMA will maintain oversight over Sub-Committee activities and direct and supervise actions taken to carry out this Plan, including by retaining decision-making authority over actions taken pursuant to the Plan to ensure such actions are necessary to address a direct threat to the national defense. The Attorney General and the Chair of the FTC will monitor activities of the Sub-Committees to ensure they execute their responsibilities in a manner consistent with this Plan and their actions have the least anticompetitive effects possible.

A. Plan of Action Execution

This Plan will be used to support the following objectives to respond to a Pandemic by maximizing the manufacture and efficient distribution of selected types of Medical Gases and creating a prioritization protocol for End-Users based upon their demonstrated or projected requirements and taking into account geographic and regional circumstances. Each Sub-Committee will undertake the following Objectives for the Medical Gases within its area of jurisdiction.

1. Objectives

(1) Optimize the timely production of sufficient quantities of Medical Gases to reduce loss of life from the COVID–19 virus.

(2) Ensure Medical Gases are distributed effectively across the whole community nationally based on risk.

(3) Balance restoration and maintenance of the nation's stockpile of Medical Gases with near-term requirements.

(4) Establish a process for FEMA Allocation of Medical Gases nationwide.

(5) Ensure ongoing competition in the manufacture and distribution of Medical Gases to the greatest extent possible under the DPA.

2. Actions

Sub-Committee Participants may be asked to support these objectives by taking the following specific actions:

(1) Assist the Chairperson in scoping each Sub-Committee and prioritizing among Sub-Committees based on each Medical Gas' importance to the national response to COVID–19 and whether it can be reasonably inferred, based upon the best evidence available, that the current and projected supply measured against current and projected demand may not adequately meet the Medical Gas requirements to all identified End-Users or regional or geographic areas of the country as result of measures taken to respond to COVID–19.

(2) Provide input to the Chairperson in creating a prioritized list of Medical Gas End-Users by categories for each type of Medical Gases identified by each Sub-Committee and ascertaining the relative demand and supply of Medical Gases among and within those End User categories. Prioritization shall be decided by the Chairperson, based upon each item's importance, reflecting the consensus views of the Sub-Committee Members that it represents the most effective way to save lives in responding to the COVID–19 pandemic. This list may be updated throughout the life of the Plan based upon either short term or long-term demands. These categories should be considered holistically in terms of the Whole-of-Nation response to COVID–19.

(3) Evaluate the domestic supply of Medical Gases and identify when the expansion of the domestic manufacture of Medical Gases may be necessary, as directed and decided by the Chairperson.

(4) Provide information, assist, and validate, as necessary as decided by the Chairperson, demand projections for Medical Gases.

(5) Create a process for and collaborate in the evaluation of competing claims for Medical Gases from End-Users.

(6) Prepare a general strategy to accomplish the activities listed in V(A)(2)(7) below regarding activities in Exigent Circumstances consistent with the decisions made by the Chairperson.

(7) In Exigent Circumstances, with review and concurrence in all possible instances by DOJ in consultation with FTC:

- Facilitate maximum availability of Medical Gases to the nation or particular geographies by deconflicting overlapping demands from the collective Participants' customer base, as directed and decided by the Chairperson.
- Facilitate maximum availability of Medical Gases to the nation or particular geographies by deconflicting overlapping supply chain demands placed upon Members, as directed and decided by the Chairperson.
- Facilitate the efficient distribution of Medical Gases by deconflicting overlapping distribution chain activities of Members, as directed and decided by the Chairperson.
- Create a process for and collaborate in the Allocation of Medical Gases nationwide or in particular geographies consistent with the decisions made by the Chairperson.
- Create a process for and collaborate in meeting any other exigent requirements throughout the nation or particular geographies consistent with the overall strategy prepared by this Sub-Committee.

(8) Provide data and information necessary to validate the efforts of the Sub-Committee including the actual and planned amounts of Medical Gases to be distributed throughout the Nation, as determined by the Chairperson.

(9) Provide feedback to the Sub-Committee on the outcomes of the collective efforts of the Sub-Committee Members and any impediments or bottlenecks.

(10) Advise the Chairperson whether additional Participants or Attendees should be invited to join this Plan and Sub-Committee.

(11) Carry out other activities regarding Medical Gases as identified by Sub-Committees under this Plan as determined and directed by the Chairperson necessary to address the COVID–19 virus' direct threat to the national defense, where such activities have been reviewed and approved by DOJ and FTC and received concurrence from Sub-Committee members.

H. Information Management and Responsibilities

FEMA will request only that data and information from Sub-Committee Participants that is necessary to meet the objectives of the Plan and consistent with the scope of the relevant Sub-Committees. Upon signing a Plan of Action Agreement for this Plan, FEMA requests that Participants endeavor to cooperate with diligence and speed, and to the extent permissible under this Plan, and share with FEMA data and information necessary to meet the objectives of this Plan.

Sub-Committee Participants agree to share with FEMA the following data with diligence and speed, to the extent permissible under this Plan, and abide by the following guidelines, where feasible and consistent with the data

that is owned by each Sub-Committee Participant:

(1) In general, Participants will not be asked to share Competitively Sensitive Information directly with other Participants.

(2) FEMA will only request direct sharing of Competitively Sensitive Information among Participants during Exigent Circumstances where there is a mission critical need or timeline such that sharing only through FEMA is impractical or threatens the outcome of the Plan or Sub-Committee action. Such requests, if made, will be only among Participants whose participation is necessary to meet the objectives of the Plan, will be limited in scope to the greatest extent possible, and will be shared only pursuant to safeguards subject to prior review and audit by DOJ and FTC. Direct sharing of Competitively Sensitive Information with other Participants will be limited in scope and circumstances to the greatest extent possible. Participants may not share Competitively Sensitive Information directly with other Participants unless specifically requested by FEMA, in consultation with DOJ and FTC. All Competitively Sensitive Information delivered to FEMA or to another Sub-Committee Participant shall be delivered by secure means, for example, password-protected or encrypted electronic files or drives with the password/key delivered by separate communication or method or via upload to an appropriately secure web portal as directed by FEMA. All data delivered to the web portal designated by FEMA is deemed to be Competitively Sensitive Information.

(3) To allow FEMA to identify and appropriately protect documents containing Competitively Sensitive Information by the Sub-Committee Participant providing the documents, the Sub-Committee Participant will make good faith efforts to designate any Competitively Sensitive Information by placing restrictive markings on documents and things considered to be competitively sensitive, the restrictive markings being sufficiently clear in wording and visibility to indicate the restricted nature of the data. The Sub-Committee Participant will identify Competitively Sensitive Information that is disclosed verbally by oral warning. Information designated as competitively sensitive will, to the extent allowed by law, be presumed to constitute confidential or privileged commercial or financial information, and be provided by the Sub-Committee Participant to FEMA with the expectation that it will be kept confidential by both parties, as such terms are understood in accordance with 5 U.S.C. 552(b)(4) of the Freedom of Information Act and federal judicial interpretations of this statute. FEMA agrees that to the extent any information designated as competitively sensitive by a Sub-Committee Participant is responsive to a request for disclosure under the Freedom of Information Act, FEMA will consult with the Sub-Committee Participant and afford the Participant ten (10) working days to object to any disclosure by FEMA.

(4) FEMA will make good faith efforts to appropriately recognize unmarked Documents containing Competitively Sensitive Information as Competitively Sensitive Information. However, FEMA cannot guarantee that all unmarked Documents will be recognized as being Competitively Sensitive Information and protected from disclosure to third parties. If the unmarked Documents have not been disclosed without restriction outside of FEMA, the Sub-Committee Participant may retroactively request to have appropriate designations placed on the Documents. If the unmarked Documents have been disclosed without restriction outside of FEMA, FEMA will, to the extent practicable, remove any requested information from public forums controlled by FEMA and will work promptly to request that a receiving party return or destroy disclosed unmarked Documents if requested by the Sub-Committee Participant.

(5) Competitively Sensitive Information may be used by FEMA, alone or in combination with additional information, including Documents and Competitively Sensitive Information received from third parties, to support FEMA's implementation of this Plan as determined by the Chairperson. In all situations, FEMA will aggregate and anonymize Competitively Sensitive Information to the greatest extent possible to protect the interests retained by the owners of the data while still allowing the objectives of the Plan and Sub-Committee to be achieved. To the greatest extent possible, such aggregation will render the competitively sensitive nature of the Competitively Sensitive Information of the Sub-Committee Participant no longer recognizable in a commercially sensitive manner, and without sufficient information to enable, by inference or otherwise, attribution to Sub-Committee Participant or its affiliates (as clearly identified and disclosed to FEMA). Any disclosure of Competitively Sensitive Information by FEMA, within or outside a Sub-Committee, will be subject to review and approval by DOJ and FTC.

(6) Except as otherwise expressly permitted by applicable federal law, FEMA shall not disclose any Competitively Sensitive Information or use any Competitively Sensitive Information for any purpose other than in connection with the purposes of this Plan, and FEMA will not sell any Competitively Sensitive Information of any Sub-Committee Participant.

(7) Except as described below, FEMA may disclose Competitively Sensitive Information only to its employees, officers, directors, contractors, agents, and advisors (including attorneys, accountants, consultants, and financial advisors). Any individual with access to Competitively Sensitive Information will be expected to comply with the terms of this Plan.

a. *Information Sharing within the Sub-Committee:* FEMA may share Competitively Sensitive Information with Sub-Committee Participants and Federal Representatives of the Plan, and their respective employees, officers, directors, contractors, agents, and advisors (including attorneys, accountants, consultants, and financial advisors) where there is a need to know and where disclosure is reasonably necessary in furtherance of implementing the Plan. FEMA will aggregate and anonymize data prior to sharing with the Sub-Committee Participants to the greatest extent possible while still allowing the objectives of the Plan to be achieved, and will not share data—particularly to competitors of the submitter—prior to consultation with and approval by the DOJ and FTC.

i. Sub-Committee Participants, when providing Competitively Sensitive Information to FEMA, may request that this Information not be shared with other Sub-Committee Participants. Where these requests are made in good faith and are reasonable in nature, FEMA will respect these requests to the greatest extent possible and will consult the owner of the data prior to any release made to Sub-Committee Participants.

b. *Restricted Reports.* FEMA may communicate Competitively Sensitive Information to appropriate government officials through Restricted Reports. The information contained in Restricted Reports shall be aggregated and anonymized to the greatest extent possible, while recognizing that these officials may need a certain amount of granularity and specificity of information to appropriately respond to COVID–19. FEMA will aim to aggregate data to the County level, and will not share Restricted Reports prior to consultation and approval from the DOJ

and FTC. FEMA may disclose Restricted Reports to relevant White House and Administration officials and State Governors, and their respective employees, officers, directors, contractors, agents, and advisors (including attorneys, accountants, consultants, and financial advisors) who have a need to know and to whom such disclosure is reasonably necessary solely in furtherance of the implementation of this Plan. FEMA shall take appropriate action (by instructions, agreement, or otherwise) to ensure that receiving parties comply with all data-sharing confidentiality and obligations under this Plan as if such persons or entities had been parties to this Plan.

c. *Public Reports.* FEMA may share information with the public through Public Reports. Data contained in Public Reports shall be fully aggregated and anonymized. Public Reports shall be aggregated to at least a state level and may be publicly disclosed after consultation and approval from the DOJ and FTC.

(8) Where possible and not obviated by Exigent Circumstances, FEMA will notify Sub-Committee Participants prior to the release of any Competitively Sensitive Information that has not been fully aggregated and anonymized. In consultation with DOJ and FTC, FEMA will consider any good-faith requests made by Sub-Committee members to hold the release of data or requests for further aggregation or anonymization. In general, FEMA will not provide notification prior to the release of *Public Reports,* under the presumption that the data in these reports has already been fully anonymized and de-identified.

(9) Any party receiving Competitively Sensitive Information through this Plan shall use such information solely for the purposes outlined in the Plan and take steps, such as imposing previously approved firewalls or tracking usage, to prevent misuse of the information. Disclosure and use of Competitively Sensitive Information will be limited to the greatest extent possible, and any party receiving Competitively Sensitive Information shall follow the procedures outlined in paragraph 7 above.

(10) At the conclusion of a Participant's involvement in a Plan—due to the deactivation of the Plan or due to the Participant's withdrawal or removal—each Participant will be requested to sequester any and all Competitively Sensitive Information received through participation in the Plan. This sequestration shall include the deletion of all Competitively Sensitive Information unless required to be kept pursuant to the Record Keeping requirements as described *supra,* Section I, 44 CFR part 332, or any other provision of law.

I. Oversight

Each Sub-Committee Chairperson is responsible for ensuring that the Attorney General, or suitable delegate(s) from the DOJ, and the FTC Chair, or suitable delegate(s) from the FTC, have awareness of activities under this Plan, including activation, deactivation, and scheduling of meetings. The Attorney General, the FTC Chair, or their delegates may attend Sub-Committee meetings and request to be apprised of any activities taken in accordance with activities under this Plan. DOJ or FTC Representatives may request and review any proposed action by the Sub-Committee or Sub-Committee Participants undertaken pursuant to this Plan, including the provision of data. If any DOJ or FTC Representative believes any actions proposed or taken are not consistent with relevant antitrust protections provided by the DPA, he or she shall provide warning and guidance to the Sub-Committee as soon as the potential issue is identified. If questions arise about the antitrust protections applicable to any particular action, FEMA may request DOJ, in consultation with the FTC, provide an opinion on the legality of the action under relevant DPA antitrust protections.

XXX. Establishment of the Sub-Committees

This Plan establishes Sub-Committees to implement the Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Medical Gases to Respond to COVID–19 to provide the Federal Government and the Participants a forum to maximize the manufacture and efficient distribution of selected types of Medical Gases and to create a prioritization protocol based upon identified types of Medical Gas End-Users and their demonstrated or projected requirements, and demonstrated or projected geographic and regional areas of need. The outcome should include a framework to expeditiously meet any Medical Gas needs in Exigent Circumstances anywhere in the Nation, and to ensure that actions to support Medical Gas stockpiling and reserves do not interfere with immediate requirements that would result in an unacceptable risk to healthcare providers or other potential Medical Gas recipients. A Sub-Committee Chairperson designated by the Chairperson will convene and preside over each Sub-Committee. Sub-Committees will not be used for contract negotiations or contract discussions between the Participants and the Federal Government; such negotiations or discussions will be in accordance with applicable federal contracting policies and procedures. However, this shall not limit any discussion within a Sub-Committee about the operational utilization of existing and potential contracts between the Participants and Representatives when seeking to align their use with overall manufacturing and distribution efforts consistent with this Plan.

Each Sub-Committee will consist of designated Representatives from FEMA, HHS, other federal agencies with equities in this Plan, and each Sub-Committee Participant. The Attorney General and Chair of the FTC, or their delegates, may also join each Sub-Committee and attend meetings at their discretion. Attendees may also be invited at the discretion of a Sub-Committee Chairperson as subject matter experts, to provide technical advice, or to represent other government agencies, but will not be considered part of the Sub-Committee.

To the extent necessary to respond to the Pandemic, only at the explicit direction of a Sub-Committee Chairperson, and subject to the provisions of Section V(B), Sub-Committee Members may be asked to provide technical advice, share information, help identify and validate places and resources of the greatest need, help project future manufacturing and distribution demands, assist in identifying and resolving the allocation of scarce resources amongst all necessary public and private sector domestic needs under Exigent Circumstances, and take any other necessary actions to maximize the timely manufacture and distribution of Medical Gases as determined necessary by FEMA to respond to the Pandemic. A Sub-Committee Chairperson or his or her designee, at the Sub-Committee Chairperson's sole discretion, will make decisions on these issues in order to ensure the maximum efficiency and effectiveness in the use of Sub-Committee Member's resources. All Sub-Committee Participants will be invited to open Sub-Committee meetings. For selected Sub-Committee meetings, attendance may be limited to designated Sub-Committee Participants to meet specific operational requirements, as determined by FEMA.

Each Sub-Committee Chairperson shall notify the Attorney General, the Chair of the FTC, Representatives, and Participants of the time, place, and nature of each meeting and of the proposed agenda of each meeting to be

held to carry out this Plan. Additionally, each Sub-Committee Chairperson shall provide for publication in the **Federal Register** of a notice of the time, place, and nature of each meeting. If a meeting is open, a **Federal Register** notice will be published reasonably in advance of the meeting. A Sub-Committee Chairman may restrict attendance at meetings only on the grounds outlined by 44 CFR 332.5(c)(1)–(3). If a meeting is closed, a **Federal Register** notice will be published within ten (10) days of the meeting and will include the reasons why the meeting is closed pursuant to 44 CFR 332.3(c)(2).

The Sub-Committee Chairperson shall establish the agenda for each meeting, be responsible for adherence to the agenda, and provide for a written summary or other record of each meeting and provide copies of transcripts or other records to FEMA, the Attorney General, the Chair of the FTC, and all Sub-Committee Participants. The Chairperson shall take necessary actions to protect from public disclosure any data discussed with or obtained from Sub-Committee Participants which a Sub-Committee Participant has identified as a trade secret or as privileged and confidential in accordance with DPA sections 708(h)(3) and 705(d), or which qualifies for withholding under 44 CFR 332.5.

XXXI. Application and Agreement

The Sub-Committee Participant identified below hereby agrees to join in the Federal Emergency Management Agency sponsored Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Medical Gases to Respond to COVID–19 under the Voluntary Agreement for the Manufacture and Distribution of Healthcare Resources Necessary to Respond to a Pandemic and to become a Participant in one or more Sub-Committees established by this Plan. This Plan will be published in the **Federal Register**. This Plan is authorized under section 708 of the Defense Production Act of 1950, as amended. Regulations governing the Voluntary Agreement for the Manufacture and Distribution for the Manufacture and Distribution of Healthcare Resources Necessary to Respond to a Pandemic and all subsequent Plans of Action at 44 CFR part 332. The applicant, as a Sub-Committee Participant, agrees to comply with the provisions of section 708 of the Defense Production Act of 1950, as amended, the regulations at 44 CFR part 332, and the terms of this Plan.

XXXII. Assignment

No Sub-Committee Participant may assign or transfer this Plan, in whole or in part, or any protections, rights or obligations hereunder without the prior written consent of the Sub-Committee Chairperson. When requested, the Sub-Committee Chairperson will respond to written requests for consent within 10 (ten) business days of receipt.

_____

(Company name)

_____

(Name of authorized representative)

_____

(Signature of authorized representative)

_____

(Date)

_____

Administrator (Sponsor)

_____

(Date)

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2021–11278 Filed 5–27–21; 8:45 am]

BILLING CODE 9111–19–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–R2–ES–2020–0119; FXES11130200000–212–FF02ENEH00]

Endangered and Threatened Wildlife and Plants; Draft Revised Recovery Plan for Houston Toad

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comment.

SUMMARY: We, the U.S. Fish and Wildlife Service, announce the availability of our draft revised recovery plan for the Houston toad, listed as endangered under the Endangered Species Act. The Houston toad is a semi-aquatic species endemic to pine and oak forests within Austin, Bastrop, Burleson, Colorado, Lavaca, Lee, Leon, Milam, and Robinson Counties, Texas. We provide this notice to seek comments from the public and Federal, Tribal, State, and local governments.

DATES: We must receive written comments on or before July 27, 2021.

ADDRESSES:

Reviewing documents: You may obtain a copy of the draft revised recovery plan in Docket No. FWS–R2–ES–2020–0119 at *http://www.regulations.gov.*

Submitting Comments: You may submit comments by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments on Docket No. FWS–R2–ES–2020–0119.
- *U.S. mail:* Public Comments Processing; Attn: Docket No. FWS–R2–ES–2020–0119; U.S. Fish and Wildlife Service Headquarters, MS: PRB/3W; 5275 Leesburg Pike, Falls Church, VA 22041–3803.

For additional information about submitting comments, see Request for Public Comments and Public Availability of Comments under **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Adam Zerrenner, Field Supervisor, Austin Ecological Services Field Office, by phone at 512–490–0057, by email at *adam_zerrenner@fws.gov,* or via the Federal Relay Service at 800–877–8339 for TTY service.

SUPPLEMENTARY INFORMATION: We, the U.S. Fish and Wildlife Service (Service), announce the availability of our draft revised recovery plan for the Houston toad (*Anaxyrus houstonensis;* formerly *Bufo houstonensis*), listed as endangered under the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*). Houston toads are endemic to aquatic and terrestrial habitats within pine and oak forests in Austin, Bastrop, Burleson, Colorado, Lavaca, Lee, Leon, Milam, and Robinson Counties, Texas. The draft revised recovery plan includes site-specific management actions and objective, measurable criteria that, when met, will enable us to remove the Houston toad from the list of endangered and threatened wildlife. We request review and comment on this plan from local, State, and Federal agencies; Tribes; and the public. We will also accept any new information on the status of the Houston toad throughout its range to assist in finalizing the recovery plan.

Background

Recovery of endangered or threatened animals and plants to the point where they are again secure, self-sustaining members of their ecosystems is a primary goal of our endangered species program and the ESA. Recovery means improvement of the status of listed species to the point at which listing is no longer appropriate under the criteria set out in section 4(a)(1) of the ESA. The ESA requires the development of recovery plans for listed species, unless such a plan would not promote the conservation of a particular species.

The Service approved the original recovery plan for the Houston toad on September 17, 1984 (Service 1984). This draft recovery plan represents the first